ID: STUDY00011386	Early Powered Mobility for Toddlers With Cerebral Palsy Using the Permobil® Explorer Mini and a Modified Ride-On Car	NCT04684576

Protocol Document
Approval Date: 12/1/2020

IRB APPROVAL OF APPLICATION

December 1, 2020

Dear Heather Feldner:

On 12/1/2020, University of Washington IRB Committee B reviewed the following application:

Type of Review:	Initial Study
Title of Study:	Early Powered Mobility for Toddlers with Cerebral Palsy: A Comparative Case Series of the Permobil® Explorer Mini and a Modified Ride-On Car
Investigator:	Heather Feldner
IRB ID:	STUDY00011386
Funding:	Name: National Institute of Child Health and Human Development (NICHD) Grant Office ID: A162382 Funding Source ID: P2C HD101912 Pass-through institution: Virginia Polytechnic Institute and State University
IND, IDE, or HDE:	None

IRB Approval

Under FWA #00006878, the IRB approved your activity.

- **Depending on the nature of your study, you may need to obtain other approvals or permissions to conduct your research. For example, you might need to apply for access to data or specimens (e.g., to obtain UW student data). Or, you might need to obtain permission from facilities managers to approach possible subjects or conduct research procedures in the facilities (e.g., Seattle School District; the Harborview Emergency Department).**
- COVID NOTE: Researchers must comply with current infection control requirements and complete a self-assessment that activities fit within allowable research as described on the HSD website.
- Your application qualified for expedited review ("minimal risk"; Categories 1, 6, & 7)).
- Under the Revised Common Rule this IRB approval is valid until study completion. In other words, there is no expiration date and you are not required to submit Continuing Review Reports to maintain your approval. However, you are still required to (1) obtain IRB approval before making any changes (modifications) to your research, and (2) provide the IRB with any Reportable New Information such as breaches of confidentiality or unanticipated problems.
- This approval applies only to the activities described in your application (including any references to specific grant sections). It does not include other activities that may be described in your grant or contract.
- This approval applies only to the generic protocol and the UW site. You will receive a separate approval notice for each additional participating site.

- Your study automatically has a Certificate of Confidentiality (CoC), because you have NIH funding. A description of the CoC protections and responsibilities has been placed in your study's Documents section.
- If you plan to continue data collection past the expiration of your NIH funding and the CoC, contact the Human Subjects Division prior to the end of your funding. We will help you determine whether you need to apply for a CoC extension.

Determinations, waivers, and regulations

The IRB made the determinations and waivers listed in the table below. Note that any granted waivers of consent or parent permission do not override a subject's refusal to provide broad consent.

Requirement	**Determination or Waiver**
Required elements of consent	Waived or altered for the initial eligibility screening
Documentation of consent	Waived for all study procedures
Involvement of children	Approved
Parental permission	Permission of only one parent is required
Documentation of parental permission	Waived
Assent	Assent is not required

Location of documents

Use the consent materials that were approved and stamped by the IRB. They can be downloaded from the Final column under the **Documents tab** in Zipline.

In addition, HSD has uploaded the following documents to the **Documents tab** in Zipline:

- Certificate of Confidentiality Acknowledgement Letter

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

Bailey Bodell, CIP
Human Subjects Reliance Administrator
4333 Brooklyn Ave NE, Box 359470, Seattle, WA 98195
p: 206.221.7918 f: 206.543.9218 bbell3@uw.edu

The Human Subjects Division (HSD) strives to ensure that people with disabilities have access to all services and content. **If you experience any accessibility-related issues with this form or any aspect of the application process, email hsdinfo@uw.edu for assistance.**

INSTRUCTIONS

- **This form is only for studies that will be reviewed by the UW IRB**. Before completing this form, check HSD's website to confirm that this should not be reviewed by an external (non-UW) IRB.
- **If you are requesting a determination** about whether the planned activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ( ). For example **1.1** must be answered.
- **Answer all questions**. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- For collaborative or multi-site research, describe only the UW activities unless you are requesting that the UW IRB provide the review and oversight for non-UW collaborators or co-investigators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

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1 OVERVIEW

Study Title: **Early Powered Mobility for Toddlers with Cerebral Palsy: A Comparative Case Series of the Permobil® Explorer Mini and a Modified Ride-On Car**

1.1 Home institution. Identify the institution through which the lead researcher listed on the IRB application will conduct the research. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **SOP: Use of the UW IRB**.*

University of Washington

1.2 Consultation history. Has there been any consultation with someone at HSD about this study?

It is not necessary to obtain advance consultation. However, if advance consultation was obtained, answering this question will help ensure that the IRB is aware of and considers the advice and guidance provided in that consultation.

☐ **No**
☒ **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

The lead PI, Heather Feldner, both emailed and spoke via phone call with HSD Team S member and IRB Reliance Administrator Jenny Maki. Jenny described the process for applying for sIRB status based on the details of our study and grant funding mechanism (NIH), and provided guidance about the nature of sIRB, UW approval processes, and required forms. She discussed our study with the Reliance team and communicated approval for UW to serve as the single IRB.

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

☐ **No**
☒ **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

Please also see active STUDY00004383, titled 'Investigating the impacts of adapted ride-on car use by children with disabilities and their families', also by PI Feldner. This expedited review study uses much of the same participant population, materials, and methods as the new study. The new study will incorporate an additional commercial pediatric powered mobility device, and a few additional outcome assessments.

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect the proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

[X] **No**
[ ] **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If this application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

The use of powered mobility devices for young children with cerebral palsy (CP) has been gaining traction, with evidence that the use of powered mobility at young ages complements (rather than detracts from) other interventions focused on more traditional mobility skills such as crawling and walking. This study will collect preliminary data (both numeric and opinion/perception data) to investigate device use patterns, caregiver perceptions, and developmental outcomes of children with CP as families are introduced to two early powered mobility interventions: the Permobil® Explorer Mini, and a modified ride-on toy car. Specific Aims include: **Aim 1:** Evaluate a powered mobility intervention to understand developmental, activity and participation outcomes of young children with CP. **Aim 2:** Compare the use patterns (frequency, duration, environment) and acceptability, feasibility, and intervention appropriateness of two powered mobility options: The Explorer Mini and a modified ride-on car.

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

This is a mixed-methods, randomized, counterbalanced AB crossover intervention study.

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

	Descriptor
☐	1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
☐	2. Part of an institution, organization, or program's own internal operational monitoring.
☒	3. Improve the quality of service provided by a specific institution, organization, or program.
☒	4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
☐	5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.
☒	6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.
☐	7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.
☐	8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)
☐	9. Expanded access use of a drug or device not yet approved for this purpose
☐	10. Use of a Humanitarian Use Device
☐	11. Other. Explain:

1.8 Background, experience, and preliminary work. Answer this question **only** if the proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Background. Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

This should be a plain language description. Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you, your team, or your collaborators/co-investigators have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: Your team has already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study being proposed in this application; your team has already done a small pilot study showing that the reading skills intervention described in this application is feasible in an after-school program with classroom aides; your team has experience with the type of surgery that is required to implant the study device; the study coordinator is experienced in working with subjects who have significant cognitive impairment.

1.9 Supplements. Check all boxes that apply, to identify relevant Supplements that should be completed and uploaded to ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	SUPPLEMENT Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	SUPPLEMENT Department of Energy

☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of the proposed research	SUPPLEMENT Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	SUPPLEMENT Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers, and the UW is being asked to provide the required certification or to ensure that the consent forms can be certified	SUPPLEMENT Genomic Data Sharing
☒	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of the proposed research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	SUPPLEMENT Devices
☒	**Multi-site or collaborative study** The UW IRB is being asked to review on behalf of one or more non-UW institutions in a multi-site or collaborative study.	SUPPLEMENT: Multi-site or Collaborative Research
☐	**Non-UW Individual Investigators** The UW IRB is being asked to review on behalf of one or more non-UW individuals who are not affiliated with another organization for the purpose of the research.	SUPPLEMENT: Non-UW Individual Investigators
☒	None of the above	

1.10 **Confirm by checking the box below** that you will comply with these basic COVID infection and risk control measures, OR that you have an exception granted by the HSD Director: (a) the only in-person interactions are essential for the study; (b) study team members and participants will wear face coverings throughout all procedures; (c) all study staff and participants will be screened for COVID-19 just prior to each research visit; and (d) no participants over the age of 85 years will be enrolled if their in-person participation is not connected with a clinical visit. See this webpage for details, including what "screening" means.

Review the HSD website for current guidelines about which in-person research activities are allowable.

☒ **Confirmed**

2 PARTICIPANTS

2.1 **Participants**. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

Participants will include children of all genders, ages 12-36 months, with diagnoses of cerebral palsy or who are at risk for cerebral palsy, and their parent or legal guardian of all genders ages 18 and above.

2.2 Inclusion and exclusion criteria.

a. Inclusion criteria. Describe the specific criteria that will be used to decide who will be included in the research from among interested or potential subjects. Define any technical terms in lay language.

Inclusion criteria for the study: 1) The child will be between 12-36 months old; 2) have a medical diagnosis of CP with any level (I-V) of associated motor ability according to the Gross Motor Function Classification System (GMFCS) or be at risk for CP according to birth history and current developmental status; 3) be able to attain a seated position with or without support; 4) be able to tolerate upright sitting with or without support while moving through space for 30 minutes; 5) and live in a household where English is spoken proficiently; Adults will 1) be 18 years or older and be the legal caregiver for the child participant; and 2) demonstrate proficiency in English. Inclusion criteria will be secured via caregiver report using screening questions.

b. Exclusion criteria. Describe the specific criteria that will be used to decide who will be excluded from the research from subjects who meet the inclusion criteria listed above. Define any technical terms in lay language.

Children will be excluded from the study if: 1) they have not been given a medical diagnosis of CP or are not at risk for CP (per parent report of birth history and current developmental status); 2) if they cannot attain a seated position with or without support; 3) if they cannot tolerate upright sitting with or without support for 30 minutes; 4) all participants will be excluded if they are not proficient in English (determined per screening process).

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

a. Will the proposed research recruit or obtain data from individuals that are known to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the WORKSHEET Prisoners for the definition of "prisoner".

[X] **No** → If no, skip the rest of part a. and continue to 2.3.b

[ ] **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and which prisons/jails:

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and/or opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. How will the chances of this be reduced?

iii. Describe what will be done to make sure that (a) recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If the research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide assurance that study team members will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole.

☐ **Confirmed**

b. Is the research likely to have subjects who become prisoners while participating in the study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

☐ **No**
☐ **Yes** → If yes, if a subject becomes a prisoner while participating in the study, will any study procedures and/or data collection related to the subject be continued while the subject is a prisoner?

☐ **No**
☐ **Yes** → If yes, describe the procedures and/or data collection that will continue with prisoner subjects

2.4 Protected populations. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that will be purposefully included. (In other words, being a part of the population is an inclusion criterion for the study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.

Population	Worksheet
☐ Fetuses in utero	WORKSHEET Pregnant Women
☐ Neonates of uncertain viability	WORKSHEET Neonates
☐ Non-viable neonates	WORKSHEET Neonates
☐ Pregnant women	WORKSHEET Pregnant Women

a. If you check any of the boxes above, use this space to provide any information that may be relevant for the IRB to consider.

N/A

2.5 Native Americans or non-U.S. indigenous populations. Will Native American or non-U.S. indigenous populations be actively recruited through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

[X] **No**

[ ] **Yes** → If yes, name the tribe, tribal-focused organization, or similar community-based organization. The UW IRB expects that tribal/indigenous approval will be obtained before beginning the research. This may or may not involve approval from a tribal IRB. The study team and any collaborators/investigators are also responsible for identifying any tribal laws that may affect the research.

2.6 Third party subjects. Will the research collect private identifiable information about *other individuals* from the study subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of the research team to readily identify the person. For example, suppose that the research is about immigration history. If subjects are asked questions about their grandparents but are not asked for names or other information that would allow easy identification of the grandparents, then private identifiable information is not being collected about the grandparents and the grandparents are not subjects.

[X] **No**

[ ] **Yes** → If yes, these individuals are considered human subjects in the study. Describe them and what data will be collected about them.

2.7 Number of subjects. Is it possible to predict or describe the maximum number of subjects (or subject units) needed to complete the study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for the specific study. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects in the context of risks and benefits. Unless otherwise specified, if the IRB determines that the research involves no more than minimal risk: there are no restrictions on the total number of subjects that may be enrolled. If the research involves more than minimal risk: The number of enrolled subjects must be limited to the number described in this application. If it is necessary later to increase the number of subjects, submit a Modification. Exceeding the IRB-approved number (over-enrollment) will be considered non-compliance.

☐ **No** → If no, provide the rationale in the box below. Also, provide any other available information about the scope/size of the research. You do not need to complete the table.

Example: It may not be possible to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that the survey will be posted for two weeks and the number who respond is the number who will be in the study.

☒ **Yes** → If yes, for each subject group, use the table below to provide the estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research *Provide numbers for the site(s) reviewed by the UW IRB and for the study-wide total number; example: 20/100*
Children with CP or at risk for CP	18
Parent/Legal Guardian	18

2.8 COVID-19 Screening. If there will be any in-person interactions with the subjects, describe how you will screen them for COVID-19 symptoms within the 24 hours before the interaction. Also, describe the COVID-19 screening procedures for the study staff who will interact with the subjects.

Acceptable procedures include some type of symptom check or attestation, or a SARS-CoV-2 test with quick access to results. Symptom attestation involves an individual reviewing a list of symptoms and declaring the presence or absence of those symptoms. HSD strongly encourages adapting this Washington State Department of Health Screening Tool https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/Employervisitorscreeningguidance.pdf or the UW EH&S Example Symptom Self-Attestation in this document: https://www.ehs.washington.edu/system/files/resources/guidance-symptom-monitoring-COVID-19.pdf. If you will test for the virus, you must also describe here whether the testing lab is CLIA-certified and how the results will be reported to the subjects.

In-person interactions will be minimal, limited to 3 visits across the study period, and may be conducted largely using social distance of 6 feet. All participants will complete a COVID symptom attestation within 24 hours prior to contact with researchers. Participants in Washington will complete the Washington State Department of Health Screening Tool. Participants in Oregon or Michigan will complete the state recommended equivalent tool for COVID screening. Research team members will also complete a COVID self-attestation within 24 hours of the study visit and will be required to wear masks and eye protection and use standard hand hygiene protocols. Adult participants will also be required to wear a mask, and children will be requested to wear a mask if possible based on age and medical status. If participants do not have their own masks, single-use, disposable masks will be provided by the research team. All hard-surface equipment provided to participants for study use will appropriately disinfected according to the UW Environmental Health & Safety protocols, prior to delivery and upon return to the research team.

3 NON-UW RESEARCH SETTING

Complete this section only if UW investigators and people named in the SUPPLEMENT: Non-UW Individual Investigators will conduct research procedures outside of UW and Harborview

3.1 Reason for locations. Describe the reason(s) for choosing the locations.

This is especially important when the research will occur in locations or with populations that may be vulnerable to exploitation. One of the three ethical principles the IRB must consider is justice: ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly, with a fair distribution of costs and potential benefits.

This study is a multi-site collaboration which involves two additional co-investigators and research sites: Dr. Sam Logan at Oregon State University, and Dr. Lisa Kenyon at Grand Valley State University. These locations have been selected due to an ongoing collaborative relationship with Drs. Logan and Kenyon, who, together with Dr. Feldner from UW have a history of research collaboration and publication in the field of early powered mobility for children with disabilities. This project allows for a diverse demographic and geographic study sample which will strengthen the rigor of our work.

3.2 Local context. Culturally appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect the research, how it is conducted, or how consent is obtained or documented.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group. In some distinct cultural groups, signing forms may not be the norm.

This federal site maintains an international list of human research standards and requirements:
http://www.hhs.gov/ohrp/international/index.html

We do not anticipate any site-specific cultural issues to impact this work.

3.3 Location-specific laws. Describe any local laws that may affect the research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

All study sites fall within US states with laws that state that age of consent is 18 yrs or older. This study does not involve the collection of health information that falls under HIPAA law. No healthcare records will be accessed and the child's diagnostic information will be provided directly by parent report to determine eligibility for the study.

3.4 Location-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect the research.

Example: A school district may require researchers to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow researchers to interview factory workers but not allow the workers to be paid for their participation.

N/A

3.5 If the PI is a student: Does the research involve traveling outside of the US?

[X] **No**

[ ] **Yes** → If yes, confirm by checking the box that (1) you will register with the **UW Office of Global Affairs** before traveling; (2) you will notify your advisor when the registration is complete; and (3) you will request a UW Travel Waiver if the research involves travel to the list of countries requiring a UW Travel Waiver.

[ ] **Confirmed**

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Recruiting and Screening. Describe how subjects will be identified, recruited, and screened. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

Participants will be recruited by the research team via social media postings, emails to known rehabilitation professionals in the WWAMI, Oregon, and Michigan areas, and via fliers hung-up and passed out at local healthcare clinics and hospitals. The research team will also send emails to past research participants who had shared their email address and had agreed to be contacted for future studies. Potential participants will self-elect to call or email the research team to hear more about the study to determine whether or not they are interested in participating. Interested potential participants would then be screened for eligibility by a member of the research team.

4.2 Recruitment materials.

a. What materials (if any) will be used to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

Written materials, such as flyers for posting and an email script will be used to recruit and screen subjects. Talking points for a phone or in-person conversation will be used. Descriptions of these materials are included as attachments to this application.

b. Upload descriptions of each type of material (or the materials themselves) to ***Zipline***. If letters or emails will be sent to any subjects, these should include a statement about how the subject's name and contact information were obtained. No sensitive information about the person (such as a diagnosis of a medical condition) should be included in the letter.

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *Provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). This means that a Modification would not be necessary if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, the description below might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3 Relationship with participant population. Do any members of the study team have an existing relationship with the study population(s)?

Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).

☐ **No**

☒ **Yes** → If yes, describe the nature of the relationship.

All investigators have done previous research work with this population and may reach out to previously known participants who meet the inclusion criteria and who have provided their written consent to be contacted about future research opportunities. None of the investigators have or will have a dual role or other type of relationship.

4.4 Payment to participants. Describe any payment that will be provided, including:

- The total amount/value
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include information about the number and amount of payments, and especially the time when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Do not include a description of any expenses that will be reimbursed.

Participants will receive monetary compensation in the amount of $75.00. This will be prorated based on $25.00 per visit for each of the three scheduled research visits, and will be delivered electronically immediately following each study visit.

4.5 Non-monetary compensation. Describe any non-monetary compensation that will be provided. Example: extra credit for students; a toy for a child. If class credit will be offered to students, there must be an alternate way for the students to earn the extra credit without participating in the research.

Child participants will receive a developmentally appropriate toy at the end of the study.

4.6 Will data or specimens be accessed or obtained for recruiting and screening procedures prior to enrollment?

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

[ ] **No** → If no, skip the rest of this section; go to question **5.1**.

[X] **Yes** → If yes, describe the data and/or specimens (including PHI) and whether it will be retained as part of the study data.

Prior to enrollment, families will be screened to ensure they meet the inclusion criteria of the study.

4.7 Consent for recruiting and screening. Will consent be obtained for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

[X] **No** → If no, skip the rest of this section; go to question **5.1**.

[ ] **Yes** → If yes, describe the consent process.

a. Documentation of consent. Will a written or verifiable electronic signature from the subject on a consent form be used to document consent for the **recruiting and screening procedures**?

☐ **No** → If no, describe the information that will be provided during the consent process and for which procedures.

☐ **Yes** → If yes, upload the consent form to ***Zipline***.

5 PROCEDURES

5.1 **Study procedures**. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), drug dosing information (if any), blood volumes and frequency of draws (if any), use of records, time required, and setting/location. If it is available: Upload a study flow sheet or table to ***Zipline***.

For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB ***POLICY: Risks of Harm from Standard Care*** *and the draft guidance from the federal Office of Human Research Protections,* ***"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";*** *October 20, 2014.*
Information about pediatric blood volume and frequency of draws that would qualify for expedited review can be found in this **reference table** *on the Seattle Children's IRB website.*

***Research Design and TImeline*:** We will conduct our work using a mixed-methods, counterbalanced AB crossover design, where intervention A is use of the Explorer Mini, and intervention B is use of the modified ride-on car. All participants at all sites will undergo the same research procedures. Participants will receive both powered mobility interventions, and randomization into two groups at each site will occur to determine which intervention participants will receive first (Modified ride-on car: n = 3; Explorer Mini: n = 3). Three research visits will be scheduled during the study. Baseline assessment (T0) will consist of initial device training and safety checkoff, interview, and administration of outcome measures. Intervention phase 1 will take place for 8 weeks, followed by a mid-study assessment (T1) at which time interviews and outcome measures will be repeated and parent perception/satisfaction with device will be assessed. Training and safety checkoff on the second device will occur. No washout period between devices is indicated because both devices provide self-initiated mobility. Intervention phase 2 will take place for 8 weeks, followed by the final study assessments (T2), where devices will be removed from the participants' homes and a final set of interviews and outcome measures will be administered. During each 8-week study phase, the researchers will conduct two virtual check-ins with each family to answer questions and provide support and standard activity suggestions for device use (i.e. open exploration, switch/joystick play, goal-directed driving).

Equipment:

Modified Ride-On Cars. Commercially available, off-the-shelf, battery-operated ride-on toy cars will be modified. ***Switch activation.*** Unmodified, a child uses their foot to press a pedal or their finger to press a small switch located on the steering wheel to activate the ride-on car which is difficult for young children with CP. Modifications of ride-on cars will include installation of an easy-to-press switch that has a large surface area and responds to a light touch for activation. ***Seating support*.** Common materials, such as PVC pipe, swimming kickboards, and Velcro will be used to build a customized supportive seating system. Seatbelts are added in all cars, and five-point harnesses are available if needed for appropriate postural support. Cars

Figure 1. Child with CP using a modified ride-on car.

operate using a rechargeable 6-volt battery, allow for 45-60 minutes of driving, and a maximum speed of 2.5 mph.

Explorer Mini. The Explorer Mini (Permobil AB, Sweden) is a commercially available, FDA approved powered mobility device intended for young children between 12-36 months of age with mobility limitations (weight limit: 35 lbs; height limit: 39.4 inches). It is lightweight (52 lbs. including battery) and fits in most automobiles (length: 25 inches; width: 19 inches; adjustable height: 29-37 inches). The Explorer Mini runs on a 12-volt battery with a driving range of 3.5 miles and a maximum speed of 1.5 mph, is controlled via a joystick with a 360-degree turning radius, has proportional speed control with 5 speed options, and can be used in a seated or standing position.

Figure 2. Child with CP using the Explorer Mini.

***Safety Training*:** A detailed device operation and safety training, home safety assessment, and check-off procedure will be completed by the research team at the initial research visit to ensure that families are ready to keep the modified ride-on car or Explorer Mini at their home and provide their child with opportunities to use the devices per the study protocol. These activities will be conducted at the first and second scheduled in-person research visits. Families will also have access to supplementary training videos throughout the study if a refresher is needed.

Dependent Measures

Aim 1: Developmental, self-care, and participation outcomes

Bayley Scales of Infant Development (BSID), 4th Edition. 30-70 minutes to administer. The BSID-IV is an internationally recognized, norm referenced set of tests designed to assess developmental domains from one month to 42 months of age. The BSID-IV includes assessment of cognitive, motor (fine motor and gross motor), social-emotional, adaptive, and language (receptive and expressive communication) subscales. All domains and subscales will be assessed. The administration of the developmental items on the Bayley will be conducted together with a researcher trained in the administration of the measure, the caregiver, and the child. Administration will be video-taped and scored at a later time in order to minimize length of in-person contact. The BSID-IV is a newly released version of the BSID-III, of which the score sheet and description are included in this application as attachments. We do not yet have access to the BSID-IV equivalents of these materials as the release of our funding to purchase the BSID IV is contingent on IRB approval. However, the differences between the III and the IV are noted in this publisher webinar (available at: https://youtu.be/Rp3QRz7qHhg) and are listed in the attached publisher presentation. These differences include shorter administration time, fewer items in several of the domains, a digital option for administration and scoring, and a more sensitive scoring scheme to identify disability. Similar to the III, the IV continues to allow for administration of structured test items in the five developmental domains described above using a standard kit, direct observation of behaviors and milestones, and active participation of the caregiver in the evaluation process. The BSID-IV has strong psychometric properties and has been empirically validated for our study population. Once the BSID-IV has been purchased, our research team will submit the scoring and overview materials upon a subsequent IRB modification.

Child Engagement in Daily Life (CEDL). 10 minutes to complete. The CEDL is a caregiver survey tool that assesses participation in family and recreational activities and uses a 5-point Likert scale to assess frequency of participation and enjoyment of participation. The CEDL also assesses participation in self-care behaviors and uses a 5-point Likert scale to assess the degree to which the child participates in the daily self-care activities of feeding, dressing, bathing, and toileting. Caregivers will complete the CEDL remotely.

Young Children's Participation & Environment Measure (YC-PEM). 20 minutes to complete. The YC-PEM is a caregiver survey tool that has 3 sections: home, daycare/preschool, and community, with each section assessing participation and the environment. For participation items, parents are asked how often their child has

participated in different types of activities, how involved their child is when participating in activities of this type, and if parents would like their child's participation to change. For environment items, parents are asked if specific aspects of the environment facilitate or hinder their child's participation and if specific supports are available and/or adequate to support their child's participation. Caregivers will complete the YC-PEM remotely.

Aim 2: Use patterns (frequency, duration, environment) & families' perspective and experiences

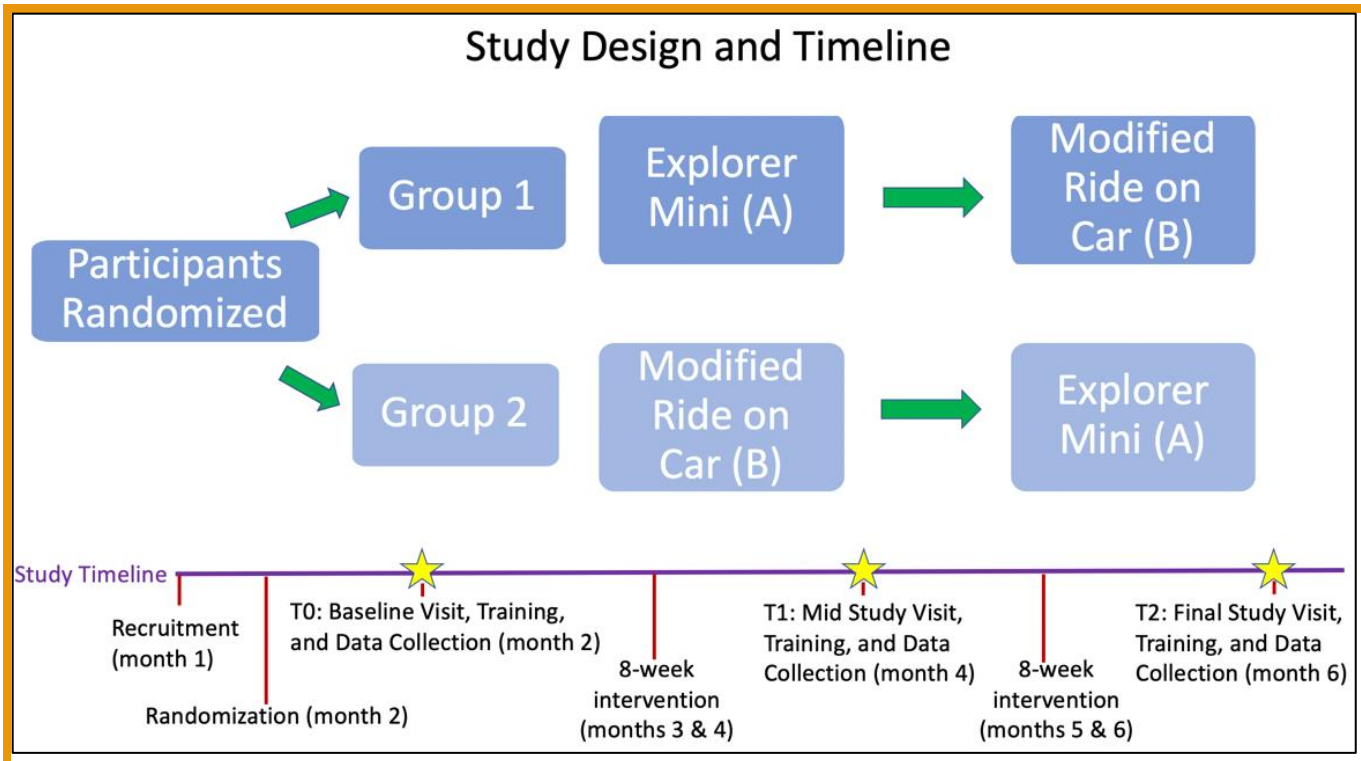
Assessment of Learning Powered Mobility Use (ALP v. 2.0). 10 minutes or less to complete. The ALP is an observational performance assessment focused specifically on stages of learning and proficiency with powered mobility devices. The tool uses eight descriptive, behavior-based categories ranging from Novice to Expert across five performance domains, including Attention, Activity and Movement, Understanding of Tool Use, Expressions and Emotions, and Interaction and Communication. These eight categories are grouped into three learning stages: Explore Function (categories 1-3), Explore Sequence (categories 4-5), Explore Performance (categories 6-8). Members of the research team will observe each child participant in their natural setting for up to 10 minutes to identify a child's performance categories and learning stage during the three scheduled research visits. They will provide each family with associated ALP strategies for facilitating device use based on the learning stage of the child. This activity may be done during the scheduled in-person visits or remotely, and will be video-recorded for scoring by the research staff at a later time.

Daily driving log. Less than five minutes to complete. Caregivers will complete a daily driving log that indicates the date, time, and environment of Explorer Mini (A) or modified ride-on car use (B). Caregivers will also make notes about the child's enjoyment level and general activities while using each device. To supplement caregiver reported data, automated device use data such as frequency and duration of activation, average speed, and distance traveled, will be collected either via a custom data logger (mounted on the modified ride-on car) or through integrated device systems (built-in to the Explorer Mini) which allow designated users (in this case, members of the research team) to access device use data via mobile Apps and secure servers. Driving logs will be completed remotely.

Semi-structured interviews. 30-45 minutes to complete. At the baseline, midpoint, and conclusion of the study a researcher will lead interviews with caregivers using a semi-structured interview guide to understand their experiences using the respective powered mobility devices, barriers encountered and solutions discovered, and perceptions of self-efficacy and behavioral capacity. Two key questions asked at each interview will provide insight as to caregiver perceptions of their child's emerging agency and powered mobility devices over time: "Can you describe [child's name] for me?" and "How do you think your child will respond/responded to power mobility device use?".[64,65] All interviews will be audio recorded and de-identified transcriptions will be created. Interviews will be conducted remotely.

Acceptability, Intervention Appropriateness, and Feasibility. 5 minutes to complete. After each intervention period, caregivers will complete a 3-measure perceptual implementation outcome survey. All measures are 4-item likert-scale surveys. The Acceptability of Intervention Measure (AIM) is designed to measure how receptive stakeholders are to adopting an intervention, the Intervention Appropriateness Measure (IAM) is designed to measure suitability of the intervention in a given environment or circumstance, and the Feasibility of Intervention Measure (FIM) is designed to measure how possible and likely stakeholders are to adopt an intervention. The AIM-IAM-FIM will be completed remotely.

Study Timeline/Flowsheet:



All sites will complete all study procedures listed above.

5.2 Recordings. Does the research involve creating audio or video recordings?

☐ **No** → If no, go to question **5.3**.
☒ **Yes** → If yes, verify that you have described what will be recorded in 5.1 and answer question **a**.

a. Before recording, will consent for being recorded be obtained from subjects and any other individuals who may be recorded?

☐ **No** → If no, email hsdinfo@uw.edu before submitting this application in Zipline. In the email, include a brief description of the research and a note that individuals will be recorded without their advance consent.

☒ **Yes**

5.3 MRI scans. Will any subjects have a Magnetic Resonance Imaging (MRI) scan as part of the study procedures?

This means scans that are performed solely for research purposes or clinical scans that are modified for research purposes (for example, using a gadolinium-based contrast agent when it is not required for clinical reasons).

☒ **No** → If no, go to question **5.4**.
☐ **Yes** → If yes, answer questions **a** through **c**.

a. Describe the MRI scan(s). Specifically:

- What is the purpose of the scan(s)? *Examples: obtain research data; safety assessment associated with a research procedure.*
- Which subjects will receive an MRI scan?
- Describe the minimum and maximum number of scans per subject, and over what time period the scans will occur. *For example: all subjects will undergo two MRI scans, six months apart.*

b. Use of gadolinium. Will any of the MRI scans involve the use of a gadolinium-based contrast agent (GBCA?)

☐ **No**

☐ **Yes** → If yes, which agents will be used? *Check all that apply.*

	Brand Name	Generic Name	Chemical Structure
☐	Dotarem	Gadoterate meglumine	Macrocylic
☐	Eovist / Primovist	Gadoxetate disodium	Linear
☐	Gadavist	Gadobutro	Macrocyclic
☐	Magnevist	Gadpentetate dimeglumine	Linear
☐	MultiHance	Gadobenate dimeglumine	Linear
☐	Omniscan	Gadodiamide	Linear
☐	OptiMARK	Gadoversetamide	Linear
☐	ProHance	Gadoteridol	Macrocyclic
☐	Other, provide name:		

1.) The FDA has concluded that gadolinium is retained in the body and brain for a significantly longer time than previously recognized, especially for linear GBCAs. The health-related risks of this longer retention are not yet clearly established. However, the UW IRB expects researchers to provide a compelling justification for using a linear GBCA instead of a macrocyclic GBCA, to manage the risks associated with GBCAs.

Describe why it is important to use a GBCA with the MRI scan(s). Describe the dose that will be used and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If a linear GBCA will be used, explain why a macrocyclic GBCA cannot be used.

2.) Information for subjects. Confirm by checking this box that subjects will be provided with the FDA-approved Patient Medication Guide for the GBCA being used in the research or that the same information will be inserted into the consent form.

☐ **Confirmed**

c. MRI facility. At which facility(ies) will the MRI scans occur? Check all that apply.

- ☐ UWMC Radiology/Imaging Services (the UWMC clinical facility)
- ☐ DISC Diagnostic Imaging Sciences Center (UWMC research facility)
- ☐ BMIC Biomolecular Imaging Center (South Lake Union research facility)
- ☐ Harborview Radiology/Imaging Services (the Harborview clinical facility)
- ☐ SCCA Imaging Services
- ☐ Northwest Diagnostic Imaging
- ☐ Other: identify in the text box below:

Personnel. For MRI scans that will be conducted at the DISC or BMIC research facilities: The role, qualifications, and training of individuals who will operate the scanner, administer the GBCA (if applicable), and/or insert and remove the IV catheter should be described in question **12.3**.

5.4 Data variables. Describe the specific data that will be obtained (including a description of the most sensitive items). Alternatively, a list of the data variables may be uploaded to ***Zipline***.

Data variables include: demographic information, developmental outcome measures (Bayley IV Scales), caregiver survey measures (YC-PEM, CEDL, AIM-FIM-IAM), powered mobility observational assessment levels (ALP), qualitative interview data, and quantitative device use data (caregiver and automated driving logs).

5.5 Data sources. For all types of data that will be accessed or collected for this research: Identify whether the data are being obtained from the subjects (or subjects' specimens) or whether they are being obtained from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

All data sources will be obtained directly from study participants.

5.6 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and the relevant compliance requirements. Review the following definitions before answering the questions:

Access *means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".*
Identifiable *means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.*
Direct identifiers *are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of data that is (when taken together) identifiable.*
Indirect identifiers *are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.*
Key *refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.*
Obtain *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from* ***accessing****, which means to view or perceive data.*

a. Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

[X] **Yes** → If yes, describe which identifiers and for which data/specimens.

Members of the research team will have access to direct identifiers via name and contact information, in order to recruit subjects. Indirect identifiers will then be assigned from a master list of subjects. The research team will have access to indirect identifiers via a subject code after consent is obtained. The research team will have access to audio recordings of interviews, video recordings of Bayley developmental assessments and de-identified study data.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

- [ ] There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before access.

☐ There is an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to study team members under any circumstances.

This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

b. Will you or any study team members obtain any direct or indirect identifiers?

☒ **Yes** → If yes, describe which identifiers and for which data/specimens.

Members of the research team will obtain direct identifiers via name and contact information, in order to recruit subjects. Indirect identifiers will then be assigned from a master list of subjects. The research team will obtain indirect identifiers via a subject code after consent is documented. The research team will obtain audio recordings of interviews and video recordings of the Bayley developmental assessments which may include direct identifiers. We will also obtain study data in the form of surveys, developmental assessments, and observational assessment which will use indirect identification.

☐ **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

☐ There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before access.

☐ There will be an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) under any circumstances.

This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

c. If any identifiers will be obtained, indicate how the identifiers will be stored (and for which data). NOTE: Do not describe the data security plan here – that information is requested in section 9.6.

[X] Identifiers will be stored with the data. Describe the data to which this applies:

Because we are collecting audio and video data, this may be inherently identifiable. This data will be stored directly on a secured and encrypted university server.

[X] Identifiers and study data will be stored separately but a link will be maintained between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

For all remaining data, each subject will be assigned an indirect identifier in the form of a participant code and pseudonym. A master list of the subject's direct and indirect identifiers will be kept separately from the data, in a locked file cabinet inside a locked office, or electronically on a secure and encrypted university server. This applies to all data collected in the study.

[ ] Identifiers and study data will be stored separately, with no link between the identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide coded information or specimens for the research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

N/A

5.7 Protected Health Information (PHI). Will participants' identifiable PHI be accessed, obtained, used, or disclosed for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***You must answer yes to this question if the research involves identifiable health care records (e.g., medical, dental, pharmacy, nursing, billing, etc.), identifiable healthcare information from a clinical department repository, or observations or recordings of clinical interactions.***

[X] **No** → If no, skip the rest of this question; go to question **5.8**

[ ] **Yes** → If yes, answer all of the questions below.

a. Describe the PHI and the reason for using it. *Be specific. For example, will any "free text" fields (such as physician notes) be accessed, obtained, or used?*

b. Is any of the PHI located in Washington State?

[ ] **No**

[ ] **Yes**

c. Describe the pathway of how the PHI will be accessed or obtained, starting with the source/location and then describing the system/path/mechanism by which it will be identified, accessed, and copied for the research. *Be specific. For example: directly view records; search through a department's clinical database; submit a request to Leaf.*

d. For which PHI will subjects provide HIPAA authorization before the PHI is accessed, obtained and/or used?

Confirm by checking the box that the UW Medicine HIPAA Authorization form maintained on the HSD website will be used to access, obtain, use, or disclose any UW Medicine PHI.

☐ **Confirmed**

e. For which PHI will HIPAA authorization NOT be obtained from the subjects?

Provide the following assurances by checking the boxes.

☐ The minimum necessary amount of PHI to accomplish the purposes described in this application will be accessed, obtained and/or used.

☐ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

☐ The HIPAA "accounting for disclosures" requirement will be fulfilled, if applicable. See UW Medicine Compliance Policy #104.

☐ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.8 Genomic data sharing. Will the research obtain or generate genomic data?

☒ **No**

☐ **Yes** → If yes, answer the question below.

a. Will genomic data from this research be sent to a national database (for example, NIH's dbGaP database)?

☐ **No**

☐ **Yes** → If yes, complete the **SUPPLEMENT Genomic Data Sharing** and upload it to ***Zipline***.

5.9 Whole genome sequencing. For research involving biospecimens: Will the research include whole genome sequencing?

Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

☐ **No**

☐ **Yes**

5.10 Possible secondary use or sharing of information, specimens, or subject contact information. Is it likely that the obtained or collected information, specimens, or subject contact information will be used for any of the following:

- Future research not described in this application (in other words, secondary research)
- Submission to a repository, registry, or database managed by the study team, colleagues, or others for research purposes
- Sharing with others for their own research

Please consider the broadest possible future plans and whether consent will be obtained now from the subjects for future sharing or research uses (which it may not be possible to describe in detail at this time). Answer **YES** even if future sharing or uses will use de-identified information or specimens. Answer **NO** if sharing is unlikely or if the only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include (for example): informal arrangements to share banked data/specimens with other investigators; establishing a repository that will formally share with other researchers through written agreements; or sending data/specimens to a third party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

☐ **No**

☒ **Yes** → If yes, answer all of the questions below.

a. Describe <u>what will be stored for future use,</u> including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

De-identified data will be stored for future use, including interview transcriptions, score report data from participation and developmental measures, and device use reports.

b. Describe <u>what will be shared with other researchers or with a repository/database/registry</u>, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

Because this study meets the criteria for an NIH clinical trial, de-identified data will be submitted to Clinicaltrials.gov.

c. Who will oversee and/or manage the sharing?

The study PI will oversee and manage the sharing until deposited with clinicaltrials.gov.

d. Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

Data will be used for scientific presentations, publications, and in future grant applications.

e. Consent. Will consent be obtained now from subjects for the secondary use, banking and/or future sharing?

☐ **No**

☒ **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in the answers to the consent questions in Section 8.

f. Withdrawal. Will subjects be able to withdraw their data/specimens from secondary use, banking or sharing?

☒ **No**

☐ **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

g. Agreements for sharing or release. Confirm by checking the box that the sharing or release will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement with the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data). Do not attach any template agreement forms; the IRB neither reviews nor approves them

☒ **Confirmed**

5.11 Communication with subjects during the study. Describe the types of communication (if any) the research team will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

Participants enrolled in the study will be contacted via email, phone, or text (as requested) about appointments for study procedures and to answer questions or provide reminders about study materials.

5.12 Future contact with subjects. Is there a plan to retain any contact information for subjects so that they can be contacted in the future?

☐ **No**
☒ **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to the study team; if not, describe who else could be provided with the contact information. Describe the criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

Contact information will be limited to the research team, and be used to either obtain additional information, or to inform subjects about other studies if they elect to be contacted.

5.13 Alternatives to participation. Are there any alternative procedures or treatments <u>that might be advantageous</u> to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

☒ **No**
☐ **Yes** → If yes, describe the alternatives.

5.14 Upload to *Zipline* all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points that will be used to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records), or video recordings.

- ***Examples**: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:** Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics that will be covered and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded**: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way**: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to the proposed research, provide a description of the process by which the data collection/questions will be established during the interactions with subjects, how the data collection/questions will be documented, the topics likely to be addressed, the most sensitive type of information likely to be gathered, and the limitations (if any) on topics that will be raised or pursued.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process that will be used for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which general approval is being sought. (See the **NOTE** bullet point in the instructions above.)

5.15 SARS-CoV-2 testing. Will the subjects be tested for the SARS-CoV-2 coronavirus?

If the only testing is to screen the subjects (question 2.8), you do not need to answer this question

[X] **No**
[ ] **Yes** → If yes:

- Name the testing lab
- Confirm that the lab and its use of this test is CLIA-certified or certified by the Washington State Department of Health
- Describe whether you will return the results to the participants and, if yes, who will do it and how (including any information you would provide to subjects with positive test results).

5.16 Research equipment and COVID-19. Does you research involve any equipment that will be used on more than one subject that is not part of a clinical facility?

Examples: a computer tablet, a portable research ultra-sound device).

[ ] **No**
[X] **Yes** → If yes: confirm by checking the box below that the disinfection and cleaning of the equipment will meet the enhanced UW Environmental Health & Safety requirements described here: https://www.ehs.washington.edu/system/files/resources/cleaning-disinfection-protocols-covid-19.pdf

[X] **Confirmed**

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does the research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State.
- The generic age of consent may be different in other states, and in other countries.

[ ] **No** → If no, go to Section 8.

☒ **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in the study population(s). If there is more than one answer, explain.

Children ages 12-36 months. Due to their young age, parental permission will be sought and consent and permission will be provided by a legal caregiver over 18 years of age.

☐ **Don't know** →This means is it not possible to know the age of the subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that is obtained from another researcher or from a government agency. Go to Section 8.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will parental permission be obtained for:

☒ All of the research procedures → Go to question **6.2b.**

☐ None of the research procedures → Use the table below to provide justification, and skip question 6.2b.

☐ Some of the research procedures → Use the table below to identify the procedures for which parental permission will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission[2]	Reason why parental permission will not be obtained	Will parents be informed about the research?[3] YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If the answer is the same for all children groups or all procedures: collapse the answer across the groups and/or procedures.*
2. *If identifiable information or biospecimens will be obtained without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will parents be informed about the research beforehand even though active permission is not being obtained?*

b. Indicate the plan for obtaining parental permission. One or both boxes must be checked.

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☒ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If both boxes are checked, explain:

6.3 Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☒ **No**

☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). The description must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

7 ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

7.1 Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

a. Will assent be obtained for:

☐ All research procedures and child groups	→ Go to question **7.2.**
☒ None of the research procedures and child groups	→ Use the table below to provide justification, then skip to question **7.6**
☐ Some of your research procedures and child groups	→ Use the table below to identify the procedures for which assent will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained	Reason why assent will not be obtained
Children ages 12-36 months	All research procedures	Reason 46.108(a)/50.55- The capability of the children is limited by age that they cannot reliably be consulted for assent. Parent consent/permission will be documented

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse your answer across the groups and/or procedures.*

7.2 Assent process. Describe how assent will be obtained, for each child group. If the research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how their comprehension of the information will be evaluated.

7.3 Dissent or resistance. Describe how a child's objection or resistance to participation (including non-verbal indications) will be identified during the research, and what the response will be.

Although we will not be seeking assent due to child age, as pediatric rehabilitation professionals the research team is well-trained to recognize signs of dissent or resistance, such as negative facial expressions or crying. When this behavior occurs, the research team will temporarily discontinue research activities and/or cue caregivers to discontinue research activities and provide a break before resuming activities. It is anticipated that these behaviors may be more prevalent at the onset of research activities and new experiences, but will diminish over time. If this does not occur, caregivers will be provided with resources and suggestions to mitigate these behaviors using play-based, developmental strategies. If these behaviors persist after these strategies are implemented, caregivers will be reminded of their right to withdraw from the study at any time.

7.4 E-consent. Will any electronic processes (email, websites, electronic signatures, etc.) be used to present assent information to subjects/and or to obtain documentation (signatures) of assent? If yes, describe how this will be done.

7.5 Documentation of assent. Which of the following statements describes whether documentation of assent will be obtained?

☐ None of the research procedures and child groups → Use the table below to provide justification, then go to question **7.5.b**

☐ All of the research procedures and child groups → Go to question **7.5.a**, do not complete the table

☐ Some of the research procedures and/or child groups

→ Complete the table below and then to go question **7.5.a**

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse the answer across the groups and/or procedures.*

a. Describe how assent will be documented. If the children are functionally illiterate or are not fluent in English, include a description of the documentation process for them.

b. Upload all assent materials (talking points, videos, forms, etc.) to ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.6 Children who reach the legal age of consent during participation in longitudinal research.

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if it was not obtained at the beginning of their participation).
Children who reach the legal age of consent: Informed consent must be obtained from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

a. Describe the plans (if any) to re-obtain assent from children.

N/A

b. Describe the plans (if any) to obtain consent for children who reach the legal age of consent.

- If adult consent will be obtained from them, describe what will happen regarding now-adult subjects who cannot be contacted.
- If consent will not obtained or will not be possible: explain why.

N/A

7.7 Other regulatory requirements. (This is for information only; no answer or response is required.) Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

Review the following definitions before answering the questions in this section.

CONSENT	is the process of informing potential subjects about the research and asking them whether they want to participate. It does not necessarily include the signing of a consent form.
CONSENT DOCUMENTATION	refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form.
CONSENT FORM	is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process.
ELEMENTS OF CONSENT	are specific information that is required to be provided to subjects.

CHARACTERISTICS OF CONSENT	are the qualities of the consent process as a whole. These are:
	• Consent must be legally effective.
	• The process minimizes the possibility of coercion or undue influence.
	• Subjects or their representatives must be given sufficient opportunity to discuss and consider participation.
	• The information provided must:
	  ○ Begin with presentation of key information (for consent materials over 2,000 words)
	  ○ Be what a reasonable person would want to have
	  ○ Be organized and presented so as to facilitate understanding
	  ○ Be provided in sufficient detail
	  ○ Not ask or appear to ask subjects to waive their rights

PARENTAL PERMISSION	is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.
SHORT FORM CONSENT	is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available.
WAIVER OF CONSENT	means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process. **NOTE**: If you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust).
WAIVER OF DOCUMENTATION OF CONSENT	means that there is IRB approval for not obtaining written documentation of consent.

8.1 Groups Identify the groups to which the answers in this section apply.

[X] Adult subjects

[X] Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2 The consent process and characteristics. This series of questions is about whether consent will be obtained for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.7. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which consent will not be obtained?

[X] **No**
[ ] **Yes** → If yes, use the table below to identify the procedures for which consent will not be obtained. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO consent process	Reason why consent will not be obtained	Will subjects be provided with info about the research after they finish? YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If the answer is the same for all groups, collapse your answer across the groups and/or procedures.*

b. Describe the consent process**,** if consent will be obtained for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names)*
- *How subjects will be provided sufficient opportunity to discuss the study with the research team and consider participation*

Consent procedures will be conducted over the phone or via Zoom video conference. Only members of the research team will obtain consent and parent permission. The research team will provide the consent and

permission form for review prior to the time of consent. All consent and permission documents and verbal explanations will be conducted using lay language, in English. Information in the consent document will be verbally explained, followed by an opportunity for the potential subjects to ask questions about the research or the consent document itself. The research team member obtaining consent will review all sections of the consent and permission document, and clearly explain that potential subjects have the option to participate or not participate in the study without penalty. After document review, the parent will be asked to provide verbal consent for themselves and permission for their child to participate in the study. The date and time of verbal consent will be documented by the research team.

c. Comprehension**.** Describe the methods that will be used to ensure or test the subjects' understanding of the information during the consent process.

During the consent process, each potential subject will be asked to repeat back the main purpose of the study, using the English language. The subject will be asked to verify that they understand they have a choice to participate or not, and asked whether they recall if and when they can withdraw from the study.

d. Influence**.** Does the research involve any subject groups that might find it difficult to say "no" to participation because of the setting or their relationship with someone on the study team, even if they aren't pressured to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

[X] **No**

[ ] **Yes** → If yes, describe what will be done to reduce any effect of the setting or relationship on the participation decision.

Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

e. Information provided is tailored to needs of subject population. Describe the basis for concluding that the information that will be provided to subjects (via written or oral methods) is what a *reasonable member of the subject population(s)* would want to know. If the research consent materials contain a key information section, also describe the basis for concluding that the information presented in that section is that which is *most likely* to assist the selected subject population with making a decision. See **GUIDANCE Key Information for Consent Materials**.

For example: Consultation with publications about research subjects' preferences, disease-focused nonprofit groups, patient interest groups, or other researchers/study staff with experience with the specific population. It may also involve directly consulting selected members of the study population.

Information provided is tailored to the needs of the participant population based on the research team's extensive experience as rehabilitation clinicians and researchers with this population, as well as consultation with publications and previous feedback from past research participants.

f. Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) that will be given to subjects to ask questions or to change their minds about participating.

Upon each subsequent research encounter, the subject will be asked for verbal confirmation of their consent to continue participating in the research, as well as be reminded that they can withdraw from the research at any time without penalty.

8.3 Electronic presentation of consent information. Will any part of the consent-related information be provided electronically for some or all of the subjects?

This refers to the use of electronic systems and processes instead of (or in addition to) a paper consent form. For example, an emailed consent form, a passive or an interactive website, graphics, audio, video podcasts. See GUIDANCE Electronic Informed Consent for information about electronic consent requirements at UW.

[ ] **No** → If no, skip to question 8.4

[X] **Yes** → If yes, answer questions **a** through **e**

a. Describe the electronic consent methodology and the information that will be provided.

All informational materials must be made available to the IRB. Website content should be provided as a Word document. It is considered best practice to give subjects information about multi-page/multi-screen information that will help them assess how long it will take them to complete the process. For example, telling them that it will take about 15 minutes, or that it involves reading six screens or pages.

The research team will provide a copy of the consent information via email, and verbally present the consent and permission document remotely via video conference (i.e. Zoom) or phone to the parent/legal guardian. The potential participant will have a chance to review an electronic copy of the consent/permission document and ask the research team questions.

b. Describe how the information can be navigated (if relevant). *For example, will the subject be able to proceed forward or backward within the system, or to stop and continue at a later time?*

c. In a standard paper-based consent process, the subjects generally have the opportunity to go through the consent form with study staff and/or to ask study staff about any question they may have after reading the consent form. Describe what will be done, if anything, to facilitate the subject's comprehension and opportunity to ask questions when consent information is presented electronically. Include a description of any provisions to help ensure privacy and confidentiality during this process.

Examples: hyperlinks, help text, telephone calls, text messages or other type of electronic messaging, video conference, live chat with remotely located study team members.

This process will occur via video conference in the same manner it would take place if using an in-person paper document.

d. What will happen if there are individuals who wish to participate but who do not have access to the consent methodology being used, or who do not wish to use it? Are there alternative ways in which they can obtain the information, or will there be some assistance available? If this is a clinical trial, these individuals cannot be excluded from the research unless there is a compelling rationale.

For example, consider individuals who lack familiarity with electronic systems, have poor eyesight or impaired motor skills, or who do not have easy email or internet access.

Sharing of study information and review of the consent and permission document is able to be conducted in person or remotely. If a participant does not have access to appropriate technology, these procedures will be conducted in person using social distance precautions. The research staff may read the document to the participant over the phone or in person should it be necessary.

e. How will additional information be provided to subjects during the research, including any significant new findings (such as new risk information) If this is not an issue, explain why.

New information will be provided to the participant via their preferred method of communication (phone, email, video conference, in-person visit)

8.4 Written documentation of consent. Which of the statements below describe whether documentation of consent will be obtained? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.7.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent

a. Is written documentation of consent being obtained for:

[X] None of the research procedures	→ Use the table below to provide justification then go to question **8.5.**
[ ] All of the research procedures	→ Do not complete the table; go to question **8.4.b.**
[ ] Some of the research procedures	→ Use the table below to identify the procedures for which written documentation of consent will not be obtained from adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will they be provided with a written statement describing the research (optional)? YES	NO
Parent participants over the age of 18 yrs	Verbal consent and permission will be conducted for all research procedures. The research team will document the date and time that verbal consent and permission was obtained.	[X]	[ ]
		[ ]	[ ]

	☐	☐
	☐	☐
	☐	☐

Table footnotes

1. *If the answer is the same for all adult groups or all procedures, collapse the answer across the groups and/or procedures.*

b. Electronic consent signature. For studies in which documentation of consent will be obtained: will subjects use an electronic method to provide their consent signature?

- *FDA-regulated studies must use a system that complies with the FDA's "Part 11" requirements about electronic systems and records. Note that the UW-IT supported DocuSign e-signature system does not meet this requirement.*
- *Having subjects check a box at the beginning of an emailed or web-based questionnaire is not considered legally effective documentation of consent.*

☒ **No**
☐ **Yes** → If yes, describe the methodology that will be used.

See the GUIDANCE Electronic Informed Consent for information about options (including the DocuSign system available through UW-IT) and requirements.

b.1 Is this method legally valid in the jurisdiction where the research will occur?

☐ **No**
☐ **Yes** → If yes, what is the source of information about legal validity?

b.2 Will verification of the subject's identity be obtained if the signature is not personally witnessed by a member of the study team? Note that this is required for FDA-regulated studies.

See the GUIDANCE Electronic Informed Consent for information and examples

☐ **No** →If no, provide the rationale for why this is appropriate. Also, what would be the risks to the actual subject if somebody other than the intended signer provides the consent signature?

☐ **Yes** →If yes, how?

b.3 How will the requirement be met to provide a copy of the consent information (consent form) to individuals who provide an e-signature?

The copy can be paper or electronic and may be provided on an electronic storage device or via email. If the electronic consent information uses hyperlinks or other websites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in the copy provided to the subjects and the website must be maintained for the duration of the entire study.

8.5 Non-English-speaking or -reading adult subjects. Will the research enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☒ **No**

☐ **Yes** → If yes, describe the process that will be used to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

a. Interpretation. Describe how interpretation will be provided, and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

b. Translations. Describe how translations will be obtained for all study materials (not just consent forms). Also, describe the method for ensuring that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

8.6 Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

a. Describe the plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if written documentation of consent is not being obtained for any part of the research.

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person before they sign it; excluding individuals who cannot read and understand the consent form.

N/A

8.7 Deception. Will information be deliberately withheld, or will false information be provided, to any of the subjects?

Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception, but not telling them ahead of time that they will be subject to an intervention or about the purpose of the procedure(s) is deception.

[X] **No**

[ ] **Yes** → If yes, describe what information and why.

Example: It may be necessary to deceive subjects about the purpose of the study (describe why).

a. Will subjects be informed beforehand that they will be unaware of or misled regarding the nature or purposes of the research? (Note: this is not necessarily required.)

[ ] **No**

[ ] **Yes**

b. Will subjects be debriefed later? (Note: this is not necessarily required.)

[ ] **No**

[ ] **Yes** → If yes, describe how and when this will occur. Upload any debriefing materials, including talking points or a script, to ***Zipline***.

8.8 Cognitively impaired adults, and other adults unable to consent. Will such individuals be included in the research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

[X] **No** → If no, go to question **8.9**.

[ ] **Yes** → If yes, answer the following questions.

a. Rationale. Provide the rationale for including this population.

b. Capacity for consent / decision making capacity. Describe the process that will be used to determine whether a cognitively impaired individual is capable of consent decision making with respect to the research protocol and setting.

b.1. If there will be repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) decision-making capacity will be re-assessed and (if appropriate) consent obtained during that time.

c. Permission (surrogate consent). If the research will include adults who cannot consent for themselves, describe the process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

*For research conducted in Washington State, see the **GUIDANCE Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".*

d. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process that will be used to obtain and document assent from the subjects.

e. Dissent or resistance. Describe how a subject's objection or resistance to participation (including non-verbal) during the research will be identified, and what will occur in response.

8.9 Research use of human fetal tissue obtained from elective abortion. Federal and UW Policy specify some requirements for the consent process. If you are conducting this type of research, check the boxes to confirm these requirements will be followed.

- ☐ Informed consent for the donation of fetal tissue for research use will be obtained by someone other than the person who obtained the informed consent for abortion.
- ☐ Informed consent for the donation of fetal tissue for research use will be obtained after the informed consent for abortion.
- ☐ Participation in the research will not affect the method of abortion.
- ☐ No enticements, benefits, or financial incentives will be used at any level of the process to incentivize abortion or the donation of human fetal tissue.
- ☐ The informed consent form for the donation of fetal tissue for use in research will be signed by both the

woman and the person who obtains the informed consent.

8.10 Consent-related materials. Upload to ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials that will be used. Materials that will be used by a specific site should be uploaded to that site's **Local Site Documents** page.

- *Translations must be submitted and approved before they can be used. However, we strongly encourage you to wait to provide them until the IRB has approved the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. URLs (website addresses) may also be provided, or written descriptions of websites. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Describe the steps that will be taken, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedure (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

Potential subjects will self-identify and self-refer to participate in the study. All subjects will be assigned a participant code and pseudonym to protect privacy.

9.2 Identification of individuals in publications and presentations. Will potentially identifiable information about subjects be used in publications and presentations, or is it possible that individual identities could be inferred from what is planned to be published or presented?

[X] **No**
[ ] **Yes** → If yes, will subject consent be obtained for this use?
- [ ] **Yes**
- [ ] **No** → If no, describe the steps that will be taken to protect subjects (or small groups of subjects) from being identifiable.

9.3 State mandatory reporting. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of the research team likely to learn of any of the above events or circumstances while conducting the research **AND** feel obligated to report it to state authorities?

[ ] **No**

[X] **Yes** → If yes, the UW IRB expects subjects to be informed of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

> Members of the research team are licensed rehabilitation professionals and considered mandated reporters of suspected or witnessed abuse. Although it is not anticipated that the research team is likely to learn of these events while conducting the research, if they are suspected or witnessed, we are obligated to report. Language describing this process is included in the consent/permission document.

9.4 Retention of identifiers and data. Check the box below to indicate assurance that any identifiers (or links between identifiers and data/specimens) and data that are part of the research records will not be destroyed until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration). If it is important to say something about destruction of identifiers (or links to identifiers) in the consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):
http://f2.washington.edu/fm/recmgt/gs/research?title=R

See the "Research Records and Data" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***https://www.uwmedicine.org/recordsmanagementuwm-records-retention-schedule.pdf***

[X] **Confirm**

9.5 Certificates of Confidentiality. Will a federal Certificate of Confidentiality be obtained for the research data?
NOTE: Answer "No" if the study is funded by NIH or the CDC, because all NIH-funded and CDC-funded studies automatically have a Certificate.

[X] **No**

[ ] **Yes**

9.6 **Data and specimen security protections**. Identify the data classifications and the security protections that will be provided for all sites where data will be collected, transmitted, or stored, referring to the **GUIDANCE Data and Security Protections** for the minimum requirements for each data classification level. ***It is not possible to answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will be applied to the data and specimens? If more than one level will be used, describe which level will apply to which data and which specimens and at which sites.

Level 3 data security protections will be used across all sites.

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. If there are any protections within the level listed in 9.6.a which will *not* be followed, list those here, including identifying the sites where this exception will apply.

10 RISK / BENEFIT ASSESSMENT

10.1 **Anticipated risks**. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how the risks will be reduced or managed. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement or reputation. For example, a breach of confidentiality might have these effects.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

The risks of participating in this study are minimal. There are no identifiable social or legal risks associated with the proposed research. Ride-on cars are a common toy and many families with small children use the cars. Similarly, the Explorer Mini is an FDA-approved Class II Medical Device commonly used for children with mobility impairments. The foreseeable risks are primarily physical or psychological risks. This study is designed to reduce known potential risks. There are no known alternative procedures that can further reduce risk and provide the same type of scientific information.
The potential risks to the subject are: 1) physical injury as a result of unsupervised device use; 2) fatigue resulting from device use; 3) electrical shock associated with battery-powered devices; 4) loss of confidentiality as a result of unauthorized access to participant data; and 5) emotional duress resulting from the discussion of potentially sensitive topics such as disability or child medical history.
To mitigate these risks, 1) subjects will undergo safety and operations training and check-offs for appropriate device use; 2) Subjects will undergo training to limit device use as appropriate based on child's individual fatigue/tolerance, and will be instructed to remove the child from the device if child is showing signs of discomfort or fatigue. 3) Any malfunctions, adjustments, repairs, or damages to the devices must be reported immediately to the research staff, and all repairs or replacements will be completed by trained research staff with expertise in engineering and rehabilitation. 4) All research-related documentation will use indirect identifiers of

subject codes and pseudonyms and be stored on a password encrypted computer and transferred to secure university servers, with the master list of subjects and subject codes stored in a separate, locked file cabinet in a locked office. 5) Subjects will be reminded at each research session that their participation is voluntary and that they do not have to answer any question that might cause discomfort or stress. Further, the researchers will discuss discontinuation of participation with the subject, should the subject demonstrate visible signs of psychological or emotional stress. Each device will be registered with the research team contact information using the manufacturer-included product registration form, to ensure direct and timely notification of any product safety warnings/recalls.

10.2 Reproductive risks. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

[X] **No** → If no go to question 10.3

[ ] **Yes** → If yes, answer the following questions:

a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

b. Steps to minimize risk. Describe the specific steps that will be taken to minimize the magnitude, probability, or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If the use of contraception will be required: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what will be done if a subject (or a subject's partner) becomes pregnant

For example; will subjects be required to immediately notify study staff, so that the study procedures can be discontinue or modified, or for a discussion of risks, and/or referrals or counseling?

10.3 MRI risk management. *Answer this question only if the subjects will receive MRI scans*. A rare but serious adverse reaction called nephrogenic systemic fibrosis (NSF) has been observed in individuals with kidney disease who received gadolinium-based contrast agents (GBCAs) for the scans. Also, a few healthy individuals have a severe allergic reaction to GBCAs.

a. Describe how the renal function of subjects will be assessed prior to MRI scans and how that information will be used to exclude subjects at risk for NSF.

b. Describe the protocol for handling a severe allergic reaction to the GBCA or any other medical event/emergency during the MRI scan, including who will be responsible for which actions.

10.4 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

[X] **No**
[ ] **Yes** → If yes, identify the procedures.

10.5 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[X] **No**
[ ] **Yes** → If yes, check all the boxes that apply.

- [ ] Administration of any drug for research purposes
- [ ] Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
- [ ] Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
- [ ] Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery
- [ ] Administration of a radio-isotope for research purposes**
- [ ] Implantation of an experimental device
- [ ] Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

<u>If any of the boxes are checked</u>:
Provide the name and institutional affiliation of a physician anesthesiologist who is a member of the research team or who will serve as a safety consultant about the interactions between the research procedures and the general or regional anesthesia of the subject-patients. If the procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member, and the Vice Chair of Clinical Research in the UW Department of Anesthesiology and Pain Medicine must be consulted in advance for feasibility, safety and billing.

*** If the box about radio-isotopes is checked: the study team is responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

10.6 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for this research, or if there is a DSMP for the research regardless of whether it is required, upload the DSMP to ***Zipline***. If it is embedded in another document being uploading (for example, a Study Protocol) use the text box below to name the document that has the DSMP. Alternatively, provide a description of the DSMP in the text box below.

This study is a clinical trial funded by the NIH. The required DSMP will be uploaded to zipline.

10.7 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or relevant study team members do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

N/A

10.8 Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

We do not anticipate the need to withdraw any participants involuntarily, however, in cases where significant and consistent emotional distress of the child or caregiver is observed by the researcher, this would warrant withdrawal from the study without consent. Because participants will be temporarily using a ride-on car and Explorer Mini Device, procedures for orderly withdrawal and removal of the devices will include: 1) written and verbal communication of set use periods for each device (8 weeks +/- 5 day grace period). Written or verbal communication of device drop off and removal plan (set date for device drop off and pickup, explain pickup and disinfection procedures).

10.9 Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

A direct benefit for participants will be to receive training, education, and trial use of two pediatric powered mobility devices.

10.10 Return of individual research results.

In this section, provide your plans for the return of individual results. An "individual research result" is any information collected, generated or discovered in the course of a research study that is linked to the identity of a research participant. These may be results from screening procedures, results that are actively sought for purposes of the study, results that are discovered unintentionally, or after analysis of the collected data and/or results has been completed.

*See the **GUIDANCE Return of Individual Results** for information about results that should and should not be returned, validity of results, the Clinical Laboratory Improvement Amendment (CLIA), consent requirements and communicating results.*

a. Is it anticipated that the research will produce any individual research results that are clinically actionable?

"Clinically actionable" means that there are established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease/condition, or lead to an improved health outcome.

In general, every effort should be made to offer results that are clinically actionable, valid and pose life-threatening or severe health consequences if not treated or addressed quickly. Other clinically actionable results should be offered if this can be accomplished without compromising the research.

[X] **No**
[ ] **Yes** → If yes, answer the following questions (a.1-a.3).

a.1. Describe the clinically actionable results that are anticipated and explain which results, if any, could be urgent (i.e. because they pose life-threatening or severe health consequences if not treated or addressed quickly).

Examples of urgent results include very high calcium levels, highly elevated liver function test results, positive results for reportable STDs.

a.2. Explain which of these results will be offered to subjects.

a.3. Explain which results will not be offered to subjects and provide the rationale for not offering these results.

Reasons not to offer the results might include:

- *There are serious questions regarding validity or reliability*
- *Returning the results has the potential to cause bias*
- *There are insufficient resources to communicate the results effectively and appropriately*
- *Knowledge of the result could cause psychosocial harm to subjects*

b. Is there a plan for offering subjects any results that are not clinically actionable?

Examples: non-actionable genetic results, clinical tests in the normal range, experimental and/or uncertain results.

[ ] **No**
[X] **Yes** → If yes, explain which results will be offered to subjects and provide the rationale for offering these results.

For qualitative interview methods, it is common to provide subjects with de-identified, aggregate data summaries of main themes or findings as a way of Member Checking, which is a technique used to ensure data accuracy and avoid researcher misinterpretation of data. Broad themes, and not individual quotes, will be shared.

c. Describe the validity and reliability of any results that will be offered to subjects.

The IRB will consider evidence of validity such as studies demonstrating diagnostic, prognostic, or predictive value, use of confirmatory testing, and quality management systems.

Member checking as described above, is part of the process of determining credibility and consistency of results, which in the qualitative research paradigm is akin to establishing validity and reliability.

d. Describe the process for communicating results to subjects and facilitating understanding of the results. In the description, include who will approach the participant with regard to the offer of results, who will communicate the result (if different), the circumstances, timing, and communication methods that will be used.

The research team will send a summary email to participants (using individual emails or BCC) describing the themes derived from the qualitative findings and encourage feedback or clarifying questions from the participants.

e. Describe any plans to share results with family members (e.g. in the event a subject becomes incapacitated or deceased).

N/A

f. Check the box to indicate that any plans for return of individual research results have been described in the consent document. If there are no plans to provide results to participants, this should be stated in the consent form.

*See the **GUIDANCE Return of Individual Results** for information about consent requirements.*

[X] **Confirmed**

10.11 Commercial products or patents. Is it possible that a commercial product or patent could result from this study?

[X] **No**

[ ] **Yes** → If yes, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

11 ECONOMIC BURDEN TO PARTICIPANTS

11.1 Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

For each institution involved in conducting the research: Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

N/A

11.2 Costs to subjects. Describe any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device; travel and parking expenses that will not be reimbursed).

There are no research-related costs to participants of the study. Devices used in the study will be temporarily provided to families at no cost.

11.3 Reimbursement for costs. Describe any costs to subjects that will be reimbursed (such as travel expenses).

N/A

12 RESOURCES

12.1 Faculty Advisor. (For researchers who are students, fellows, or post-docs.) Provide the following information about the faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

N/A

12.2 UW Principal Investigator Qualifications. Upload a current or recent Curriculum Vitae (CV), Biosketch (as provided to federal funding agencies), or similar document to the Local Site Documents page in Zipline. The purpose of this is to address the PI's qualifications to conduct the proposed research (education, experience, training, certifications, etc.).

For help with creating a CV, see http://adai.uw.edu/grants/nsf_biosketch_template.pdf and https://education.uwmedicine.org/student-affairs/career-advising/year-4/residency-applications/curriculum-vitae/

[X] **The CV will be uploaded.**

12.3 UW Study team qualifications. Describe the qualifications and/or training for each UW study team member to fulfill their role on the study and perform study procedures. (You may be asked about non-UW study team members during the review; they should not be described here.) You may list these individuals by name, however if you list an individual by name, you will need to modify this application if that individual is replaced. Alternatively, you can describe study roles and the qualifications and training the PI or study leadership will require for any individual who might fill that role. The IRB will use this information to assess whether risks to subjects are minimized because study activities are being conducted by properly qualified and trained individuals.

Describe: The role (or name of person), the study activities they will perform, and the qualifications or training that are relevant to performing those study activities.

Examples:
Research Study Coordinator: Obtain consent, administer surveys, blood draw. Will have previous experience coordinating clinical research and be a certified phlebotomist in WA.
Undergraduate Research Assistant: Obtain consent, perform all study procedures. Will have had coursework in research methods, complete an orientation to human subjects protections given by the department, and will receive training from the PI or the graduate student project lead on obtaining consent and debriefing subjects.
Acupuncturist: Perform acupuncture procedures and administer surveys. Must be licensed with WA State DoH and complete training in administering research surveys given by the project director, an experienced survey researcher.
Co-Investigator: Supervise MRI and CT scan procedures and data interpretation, obtain consent. MD, specialty in interventional radiology and body imaging. 5-years clinical research experience.

Research Study Coordinator: Perform eligibility screening, obtain consent, administer surveys, maintain communication with families. Will have previous experience coordinating clinical research.
Undergraduate or Graduate Research Assistant: Perform screenings, obtain consent, perform all study procedures. Will have had coursework in research methods, complete an orientation to human subjects protections given by the department, and will receive training from the PI regarding all study procedures.

Co-Investigator: Obtain consent, perform all study procedures. Will be a licensed rehabilitation professional (i.e. PT or OT and/or a PhD level investigator with required human subjects research training and past experience participating in or leading human subjects research.

12.4 Study team training and communication. Describe how it will be ensured that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

Each member of the research team has a current CITI training certificate, and are versed in the management of subject data and ethics involved in human subjects research. Regular team meetings will occur throughout the research to ensure all team members are appropriately informed about the research procedures and data, as well as any unanticipated changes. Bi-monthly progress meetings will be held with all members of the research team.

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

UW will serve as the single IRB administrator for this study, and the UW HSD Reliance Team will coordinate additional approvals or permissions directly with Oregon State University and Grand Valley State University.

13.2 Financial Conflict of Interest. Does any UW member of the team have ownership or other Significant Financial Interest (SFI) with this research as defined by UW policy GIM 10?

☒ **No**

☐ **Yes** → If yes, has the Office of Research made a determination regarding this SFI as it pertains to the proposed research?

- ☐ **No** → If no, contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination
- ☐ **Yes** → If yes, upload the Conflict Management Plan for every UW team member who has a FCOI with respect to the research, to ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research and include the FIDS Disclosure ID if available.