Title	Novel Gait Training Paradigm to Promote Healthy Aging in Individuals with Cerebral Palsy
IRB Institution	University at Buffalo
IRB Approval period	3/7/22-3/6/23

Complete Research Protocol (HRP-503)

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PROTOCOL TITLE:

Include the full protocol title.

Response: Novel Gait Training Paradigm to Promote Healthy Aging in Individuals with Cerebral Palsy

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response:

Jiyeon Kang, PhD

Dept. of Mechanical and Aerospace

Room 1011 Furnas Hall, Buffalo, NY 14260

Phone: (716) 645 6063

Fax: (716) 645 2883

jiyeonk@buffalo.edu

VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response: 1

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	10/7/2021	Pre/post evaluation measures	No

FUNDING:

Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.

Response: *2019-20 SUNY Research Seed Grant Program RFP #20-02-RSG*

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response: *2019-20 SUNY Research Seed Grant Program RFP #20-02-RSG* Aim 2 Investigate the potential of reinforcing the retention of cable-actuated training by providing auditory feedback to eight adults with cerebral palsy

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response: The copies of IRB correspondence or signed consent forms will be stored in a locked cabinet located in Furnas Hall Room 809. Only personnel related to the project will have access to the document.

Location: Cabinet with key access

Address: Room 809 Furnas Hall, Buffalo, NY 14260

Department: Dept of Mechanical and Aerospace Engineering

1.0 Study Summary

Study Title	Novel Gait Training Paradigm to Promote Healthy Aging in Individuals with Cerebral Palsy
Study Design	Adults with cerebral palsy will be recruited to conduct the feasibility testing of our hypothesis for multiple training sessions.
Primary Objective	The purpose of this study is to create a platform to prolong the adaption obtained from the cable-actuated gait training and encourage the individuals with CP to provide self-care at home.
Secondary Objective(s)	Investigate the potential of reinforcing the retention of cable-actuated training by providing auditory feedback to adults with cerebral palsy
Research Intervention(s)/ Investigational Agent(s)	This study includes cable-actuated strength training and auditory feedback to reinforce the feedback.
IND/IDE #	N/A
Study Population	Adults with Cerebral Palsy
Sample Size	20

Study Duration for individual participants	2 Years
Study Specific Abbreviations/ Definitions	sEMG: surface electromyography DOF: degree of freedom CP : cerebral palsy

2.0 Objectives*

2.1 Describe the purpose, specific aims, or objectives of this research.

Response: (1) Investigate the benefit of the strength training of adults with cerebral palsy using a cable-actuated robot.
(2) Investigate the potential of reinforcing the retention of cable-actuated training by providing auditory feedback to eight adults with cerebral palsy.

2.2 State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response:

(1) We hypothesized that individuals with cerebral palsy will benefit from the cable-actuated strength training to improve their walking ability and posture.

(2) We hypothesized that auditory feedback will reinforce the retention of cable-actuated training.

3.0 Scientific Endpoints*

2.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should ***not*** *be a date.*

Response: The two primary outcome measures will be the motion and the muscle activation data of the lower body during walking. Motion trajectory will be used to detect the changes in the kinematics and sEMG data will present the muscle activation of the participants. Ground reaction force, center of pressure, and center of mass will be evaluated with the instrumented insole and treadmill. Before the first and after the last training, participants will be evaluated for functional gait assessment, 6-min-walk, leg strength using dynamometer, international physical activity questionnaire (short form), usability questionnaire, and Modified Ashworth test by a physical therapist. This will show the kinematic and kinetic changes of the participant after the training.

4.0 Background*

4.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Response: Cerebral palsy is a neurological disorder that occurs around birth, impairing movement and posture which leads to critical limitations in their daily lives. About 3.6 children out of every 1000 school-aged children are diagnosed with cerebral palsy [1], and their life expectancy is significantly increased due to the advanced medical technology [2]. Past research has primarily focused on children with cerebral palsy to restore their motor function. Comparatively, attention to the adult with CP has been sparse and the evolution of the motor disorder through adulthood has not been well understood [3]. It is suggested that individuals with CP age prematurely, demonstrating early declines in physical function and mobility, presumably due to the changes in strength, flexibility, and endurance [3]. Therapeutic services have primarily been designed for children with CP without considering longer-term aging with a disability. There is a need to develop interventions that are adult-focused and can improve the motor function of individuals aging with CP.

Deterioration of locomotion skills is a major problem in persons with CP. This can lead to a sedentary lifestyle at an early age and a significant decrease in the quality of life [4]. A few studies have addressed progressive resistive strength and aerobic training in adults with CP which show significant strength improvements in their walking ability and gait parameters [5]. As an extension of these studies, we investigated the use of targeted gait training using a cable-actuated system over a treadmill that promoted strengthening during walking in children with CP [6]. This cable-actuated system provided downward force and participants had to extend their legs against the force while walking on a treadmill. This leads to a straighter walking posture, longer stride, and reduced toe-walking pattern in a supervised environment. Once the participants were taken out of the actuated cable system, they showed immediate improvement of knee extension and heel-to-toe walking. This is because participants recalibrated their movement to walk against the downward force and its effect lasted for a while after the force was removed. This after-effect of adaptation may be used in physical therapy to let the patients experience a more normal movement pattern [7]. In the proposed study, we will introduce the use of instrumented insoles to provide feedback to sustain positive after-effects in unsupervised ecological environments. Sensory feedback has been shown to improve the gait features of individuals with cerebral palsy in the past [8, 9, 10]. We will use similar methods to assist adults with CP to retain the positive motor adaptation from using the cable-actuated system on the treadmill. We will collect pressure data, foot clearance, heel-to-toe pattern from smart insoles and provide feedback to the participant on their gait pattern. We

hypothesize that once participants have experienced gait in response to resisted gait training, the feedback from the insoles will assist them to maintain the improved gait. Furthermore, we hypothesize that the use of sensory feedback with minimal supervision will lead these individuals to take an active role in their gait training. It can foster collaboration between the therapist and participant in the shared goal of improved gait quality. These are essential components of self-management, especially important for individuals with chronic conditions like cerebral palsy.

The goal of the suggested work is to retain the positive after-effects of resistive gait training for longer periods using sensory feedback until it becomes the normal gait pattern by repeated and reinforced training. For the first time, we will examine the feasibility of using sensory feedback to reinforce the adaptation from the resisted gait training. Previous robotic devices focused on the adaption itself during the training, but methods on sustaining the adaptation after the training have not been well studied, despite the significance of maintaining the adaptation. Different types of auditory feedback will be explored using the data from smart insoles to extend the carry-over effect of motor adaption during training. The knowledge of this study can be widely used in other rehabilitation devices to sustain and maximize the training effect. Secondly, this approach creates a rehabilitation platform that includes both supervised and unsupervised training which can lead to the participant taking a more active role in their care. Once participants step off the treadmill, they will use the instrumented insoles and the sensory feedback to maintain positive gait changes from the gait-resisted training. By suggesting a training method collaborating in-clinic, we envision a successful therapeutic intervention that is tailored to the needs of an adult with CP. It provides in-clinic gait resisted training to safely provide a stimulus that can alter their gait. The proposed study would also create a rich biomechanical data set over the whole gait cycle of adults with CP. Since this is an understudied population, this information would be invaluable to clinicians and researchers. This data set will help to understand neuromechanical characteristics of the gait of adults with CP for future implications in physical and pharmacological interventions, and as the long-term mission to promote healthy aging in the population with cerebral palsy by improving their functional mobility.

4.2 Include complete citations or references

Response:

[1] M. Yeargin-Allsopp, K. N. Van Braun, N. S. Doernberg, R. E. Benedict, R. S. Kirby, and M. S. Durkin, “Prevalence of cerebral palsy in 8-year-old children in three areas of the united states in 2002: A multisite collaboration,” Pediatrics, 2008, doi: 10.1542/peds.2007-1270.

[2] D. Wilson-Costello, H. Friedman, N. Minich, A. A. Fanaroff, and M. Hack, “Improved survival rates with increased neurodevelopmental disability for extremely low birth weight infants in the 1990s,” Pediatrics, 2005, doi: 10.1542/peds.2004-0221.

[3] P. Haak, M. Lenski, M. J. C. Hidecker, M. Li, and N. Paneth, "Cerebral palsy and aging," Developmental Medicine and Child Neurology. 2009, doi: 10.1111/j.1469-8749.2009.03428.x.

[4] Jahnsen R, Villien L, Egeland T, Stanghelle JK, Holm I. Locomotion skills in adults with cerebral palsy. Clin Rehabil. 2004 May;18(3):309-16. doi: 10.1191/0269215504cr735oa. PMID: 15137562.

[5] D. Thorpe, "The role of fitness in health and disease: Status of adults with cerebral palsy," Developmental Medicine and Child Neurology. 2009, doi: 10.1111/j.1469-8749.2009.03433.x.

[6] J. Kang, D. Martelli, V. Vashista, I. Martinez-Hernandez, H. Kim, and S. K. Agrawal, "Robot-driven downward pelvic pull to improve crouch gait in children with cerebral palsy," Sci. Robot., 2017, doi: 10.1126/scirobotics.aan2634.

[7] L. A. Malone and A. J. Bastian, "Thinking about walking: Effects of conscious correction versus distraction on locomotor adaptation," J. Neurophysiol., 2010, doi: 10.1152/jn.00832.2009.

[8] van Gelder LMA, Barnes A, Wheat JS, Heller BW. The use of biofeedback for gait retraining: A mapping review. Clin Biomech (Bristol, Avon). 2018 Nov;59:159-166. doi: 10.1016/j.clinbiomech.2018.09.020. Epub 2018 Sep 20. PMID: 30253260.

[9] Ghai S, Schmitz G, Hwang TH, Effenberg AO. Auditory Proprioceptive Integration: Effects of Real-Time Kinematic Auditory Feedback on Knee Proprioception. Front Neurosci. 2018;12:142. Published 2018 Mar 8. doi:10.3389/fnins.2018.00142

[10] M. Batavia, J. G. Gianutsos, A. Vaccaro, and J. T. Gold, "A do-it-yourself membrane-activated auditory feedback device for weight bearing and gait training: A case report," Arch. Phys. Med. Rehabil., 2001, doi: 10.1053/apmr.2001.21931.

5.0 Study Design*

5.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response: The experiment protocol involves a maximum of ten sessions and will take two or three hours for each session. Baseline data will be collected before the first session for both overground and treadmill walking. During this session, the sound level will be adjusted based on the feedback received from the users. The researcher will ask the comfortable sound level to the participant before starting the experiment. Training will be conducted on the treadmill with the cable-actuated device for about 20 minutes. When the cables were removed, participants walked on the treadmill for 4 minutes during the post-training session. During training and post-training, participants will be exposed to feedback while walking on the treadmill. After treadmill walking, CP participants will be asked to take a ten-minute break and then practice overground walking for two minutes with auditory feedback (type A) and without it (type B). Effects of 3 different types of

auditory feedback will be explored namely, rhythmic sounds, movement sonification, and sound notifying erroneous gait. Group A participants will be further divided into groups depending on the type of auditory feedback that will be provided. Participants will participate in a maximum of 10 sessions, two or three times a week. Before the first and after the last training, participants will be evaluated for functional gait assessment, 6-min-walk, leg strength using a dynamometer, international physical activity questionnaire (short form), usability questionnaire, and Modified Ashworth test by a physical therapist.

6.0 Study Intervention/Investigational Agent

1.1 Description: *Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.*

Response:

A cable-actuated system that can apply a therapeutic force while walking was developed in our past study. The system consists of motorized cables, belt, and tension sensors to apply a downward force to strengthen the legs. During the training, participants powered soleus muscles more and changed the coordination of gastrocnemius muscles. Six children with crouch gait and diplegia participated in the experiment for 15 sessions. After 15 sessions, six children with CP presented better foot clearance, heel-toe pattern, and straighter walking posture during the stance. These children also showed immediate change when the cables were removed by recalibrating their CNS against the downward force. To walk against the resistance force, children provide feedforward control of their anti-gravity muscles to create larger upward force. When the cables were removed, they still kept the increased muscle force which resulted in stronger stride, heel-toe pattern, and foot clearance [1]

Our smart insoles have shown the capability to provide a full gait monitoring strategy during daily life [2]. This system is fully portable and equipped with pressure sensors, an IMU, a microcontroller, a Bluetooth module, and a battery. An array of pressure sensors is integrated into the insole to measure the pressure distribution with an IMU to provide the posture of the foot. The device can provide spatiotemporal gait parameters, pressure distribution, the center of pressure, and foot clearance with a wireless system and mobile application. The unique design of the pressure sensor allows detecting abnormal foot contact with the ground which is typically found in patients with a neurological movement disorder. The shoe was tested on stroke patients and the elderly to monitor their gait patterns in real-time. Using the insole, we will measure the gait characteristics of the individuals such as gait parameters, ground reaction force, the center of pressure to provide auditory feedback [3]. An instrumented treadmill manufactured by Bertec will also be used as a backup in case we face technical issues with the smart insole [4]. The instrumented treadmill allows for highly accurate 6-axis load measurement for each lower limb.

Furthermore, using the data from the smart insole and Bertec Force plate instrumented treadmill, three different types of auditory feedback will be provided to the selected participants. The sound level of the auditory feedback is adjustable and will be determined based on the user's feedback during the baseline trials. Rhythmic auditory feedback will be generated to provide participants information about the cadence which will help them synchronize their footsteps. Another type of auditory feedback consists of, an unpleasant sound which will be generated in case the gait characteristics such as knee flexion or ankle plantarflexion of the participants abnormal. The last type of auditory feedback will comprise modulating the characteristics such as pitch and tempo of the sound to reflect the motion of the lower limbs[5]. Analyzing the effects of these different types of auditory feedback will not only allow us to identify if auditory feedback aids in the retention of benefit from strength training for a longer duration but also identify the varying degrees of effects of different types of auditory feedback on retention of gait adaptations from cable actuated robot.

[1] J. Kang, D. Martelli, V. Vashista, I. Martinez-Hernandez, H. Kim, and S. K. Agrawal, "Robot-driven downward pelvic pull to improve crouch gait in children with cerebral palsy," Sci. Robot., 2017, doi: 10.1126/scirobotics.aan2634.

[2] Yang, Zhuolin, et al. "A smart environment-adapting timed-up-and-go system powered by sensor-embedded insoles." IEEE Internet of Things Journal 6.2 (2018): 1298-1305.

[3] Yang, Zhuolin, et al. "A smart environment-adapting timed-up-and-go system powered by sensor-embedded insoles." IEEE Internet of Things Journal 6.2 (2018): 1298-1305.

[4] Instrumented
Treadmills, URL:- https://www.bertec.com/products/instrumented-treadmills

[5] Schaffert, Nina, et al. "A review on the relationship between sound and movement in sports and rehabilitation." Frontiers in psychology 10 (2019): 244.

6.1 Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

- *If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.*

Response: N/A

6.2 If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

- *Identify the holder of the IND/IDE/Abbreviated IDE.*
- *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response: N/A

7.0 Local Number of Subjects

7.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response: 20

7.2 If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response:

7.3 Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response: **Cerebral Palsy is the most common of all childhood disabilities, affecting approximately three live births out of every thousand in the United States. With the population of Erie County being over 900,000, it is feasible to identify 20 adults with CP to participate in the study.**

8.0 Inclusion and Exclusion Criteria*

*8.1 Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response: The inclusion criterion for the study is adults with cerebral palsy (18-65 years old) who can ambulate a distance of 100 feet with or without the use of assistive devices. However, they shouldn't need physical assistance from a caregiver while they walk 100 feet.

*8.2 Describe the criteria that define who will be **excluded** from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response: Recruited participants will be excluded if they have severe Equinovarus foot or Genu recurvatum of the knee. Participants who had surgery within 6 months will be excluded. Individuals with pregnancy, lower limb prosthetics, severe respiratory problems such as chronic obstructive pulmonary disease, heart disease, a loss of sensation, uncontrolled blood pressure, a seizure disorder, severe arthritis will be excluded from this study.

8.3 Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response:

☐ Adults unable to consent

☐ Individuals who are not yet adults (infants, children, teenagers)

☐ Pregnant women

☐ Prisoners

*8.4 Indicate whether you will include non-English speaking individuals in your study. **Provide justification if you will exclude non-English speaking individuals.***

*In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may **not** be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous

questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response: We will exclude non-English speaking individuals as we don't have human resources for translation. All instructions should be equally provided to the user for consistency.

9.0 Vulnerable Populations*

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

9.1 For research that involves ***pregnant women,*** *safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response:

☒ **N/A**: This research does not involve pregnant women.

9.2 For research that involves ***neonates of uncertain viability or non-viable neonates,*** *safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

9.3 For research that involves ***prisoners****, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

9.4 For research that involves ***persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")****, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

☒ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

*9.5 For research that involves **cognitively impaired adults**, safeguards include: NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)*

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

*9.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. **Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response: Students may be recruited in this study, but cable actuated training and observing their gait with sEMG sensors, reflective markers, or IMUs won't create any risks. They are allowed to stop and take breaks during the study anytime if they need it. Students will be explicitly informed that their grades in any course will not be affected, positively or negatively, based on your participation in this study

10.0 Eligibility Screening*

*10.1 Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

📎 *Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).*

Response: *Dr. Langan is a licensed physical therapist. She will perform screening procedures for the patients. We will examine the individual's ability to ambulate 100 feet with or without assistive devices but not with the assistance of a caregiver to ensure independent walking through the protocol.*

☐ **N/A:** There is no screening as part of this protocol.

11.0 Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

11.1 Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

Response: Extensive distribution of flyers through organizations such as WNY parent's network, UB boards that allow study flyers, clinical

facilities in the greater Buffalo region, and clinicians that see patients with CP. The Buffalo Research Registry (BRR) is a database of people from Buffalo and Western New York who have shown interest in becoming research study volunteers. We will ask for a list of potential participants from the BRR. A flyer providing information on the study will be emailed or mailed to potential participants from this list.

11.2 Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response: Participants will self-select to respond to one of the flyers for the study. They need to choose to contact the researchers to participate in the study. The settings for the phone conversation and data collection will be private areas. *The researcher will emphasize that participation in this study is voluntary and subjects may withdraw at any time with no consequences.*

11.3 Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response: F*lyers and* follow-up phone conversations when participants demonstrate an interest in the study.

12.0 Procedures Involved*

*12.1 Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in your response.

Response: Participants will be scheduled for an appointment to visit AWEAR (Assistive Wearable Robotics) lab which is located at University at Buffalo Furnas Hall Room 809 or Kimball 115. They will be asked to wear comfortable clothing which won't restrict their natural movement. Participants are required to wear reflective markers on the whole body to record the motion by a Vicon motion capture system. Similarly, Delsys surface electromyography sensors will be attached to the skin of the participant to record the muscle activation during walking. The instrumented insole will also be added to the participant's shoes. The participant will walk on the treadmill for 5 minutes as warming-up and 20-minutes

of training with a cable-actuated robot will be provided. The device will augment 15% of their own body weight. While they are walking with the device, auditory feedback will be provided for the participants who are assigned to the auditory group. The auditory and non-auditory groups will be randomly assigned. Furthermore, one of the 3 different types of auditory feedback will be randomly assigned to participants from the feedback group. A break of 5 minutes will be provided after 10 minutes of walking with the device. After the robotic training is completed, the device will be taken off and the participant will walk without the device to monitor the immediate retention of the training. After every 10 minutes, the researcher will ask the participant questions as per the Borg exertion scale to check the fatigue of the participant. After finishing the treadmill session, participants will take a 10-minute break and walk 4 minutes with (or without auditory feedback) on the floor. The participant will repeat overground walking for a total of three sets. There will be a total of ten training sessions, two or three sessions a week and each session will last for a maximum of 3 hours. In addition, pre and post-training visits are required to evaluate functional gait assessment, 6-min-walk, leg strength using a dynamometer, international physical activity questionnaire (short form), usability questionnaire, and Modified Ashworth test by a physical therapist.

12.2 Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response:

• We will schedule the participants to visit the lab. We will make a table when the participants are available.

• *EMG data from the muscles*

• *Vicon motion capture data*

• *Photo and Video of the test*
• *IMU sensor data*

• *Smart insole data*
• *Ground reaction force*

12.3 List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).

Include copies of these documents with your submission.

Response: Vicon motion capture system, Delsys Trigno sEMG system, and Bertec Force plate instrumented treadmill, Smart Insole

12.4 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

Response: N/A

*12.5 Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

Response: N/A

*12.6 Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response: The data and study results will be not shared with the subject.

13.0 Study Timelines*

13.1 Describe the anticipated duration needed to enroll all study subjects.

Response: All data will be collected in two years of a time window.

13.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response: Maximum of three hours will be used to collect the data

13.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response: We expect to collect and analyze the data within three years.

14.0 Setting

14.1 Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response: Dr. Kang's laboratories are located in 809 Furnas and 115 Kimball. The laboratories are equipped with a Vicon motion capture system, Delsys sEMG system, smart insole, Kinect cameras, and Bertec Force plate instrumented

treadmill. A computer station can control Vicon, Delsys, Bertec system, and smart insole all together simultaneously.

14.2 For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response:

☒ **N/A:** This study is not conducted outside of UB or its affiliates.

15.0 Community-Based Participatory Research

15.1 Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

15.2 Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

16.0 Resources and Qualifications

*16.1 Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response:

The principal investigator has various experiences to collect biomechanical data of healthy individuals, Parkinson's disease, and cerebellar ataxia patients. PI has been published experiments that include motion capture systems and sEMG systems. All researchers who are working with PI will finish CITI program training to establish a basic knowledge of human subjects research.

Describe other resources available to conduct the research.

16.2 Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response: We estimate that the PI will devote 20% of their time to the study. Other PIs will devote 5s% of their time to the study. The research assistance will devote 30% of their time to the study.

16.3 Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response: There will be a licensed physical therapist (Dr. Jeanne Langan or other physical therapist) when we conduct this study.

16.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response: PI will train all personnel who will conduct human subject studies. Their role will be assigned and informed about the protocol, procedures, and duties. Before starting this study, all staff members will run a dry-run test to practice their knowledge.

17.0 Other Approvals

17.1 Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response:

☒ **N/A:** This study does not require any other approvals.

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response: Participants will be assigned an unidentifiable code when analyzing the data. During the study, the participant can ask questions anytime or stop the study.

18.2 Indicate how the research team is permitted to access any sources of information about the subjects.

*NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question **does apply** to records reviews.*

Response: *All data collection occurs after the subject has signed the consent form.*

19.0 Data Management and Analysis*

19.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response: The collected motion capture data will be labeled and filtered with a 4th order Butterworth filter. All sEMG data will be post-processed by bandwidth filter, enveloped, smoothed, and scaled. To define the beginning and the end of each repetition the speed of the markers is used as a threshold. The data will be time-scaled and averaged over different trials.

The analyses for CP subjects are carried out separately. Descriptive statistics will be obtained to compare the randomized groups on baseline factors including pre-existing chronic conditions, underlying disease, demographics, and other potential confounders. When the numeric data are not normally distributed based on graphic inspection (e.g., normal quantile plots), we will consider the Box-Cox transformation. For numeric data, a mixed-effects model will be constructed, where

major factors include the effect of time within each day, the effect of feedback, the effect of the day as well as the effect of the random assignment. Major statistics to obtain will be improvement measures between baseline and the end of treatment. An appropriate covariance structure will be considered reflecting the correlations within subjects. Various contrasts will be tested to see an improvement by the major factors. Some other covariates such as demographic and other subjects characteristics can be included in the models if a significant difference is shown. Residual plots will be examined to check the normality of the residual. If not normally distributed, we will consider simpler nonparametric methods that compare specific factor combinations in a form of various contrasts. For categorical data, we will construct a similar model to the numeric data, except that we will use an appropriate link function based on the generalized linear model. The covariance structures will be incorporated into the analysis using a generalized structural equation modeling strategy. For this pilot study, we do not consider controlling family-wise Type I error as the purpose of the study is to see the viability of the treatment and potentially support the bigger clinical trials in the future.

19.2 If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response: A goal of this study is to test the feasibility and efficacy of the proposed intervention in the improvement of gait characteristics. Currently, no previous study is available to have the treatments both resistance training and sensory feedback. For CP subjects, we will have a sample size of 20 (10 each group), which requires an effect size of 0.5 to have a power of 80% with the size of the test 0.05 in the two-group comparison with 6 repeated measures under the assumption of compound symmetry with auto-correlation 0.1.

19.3 Describe any procedures that will be used for quality control of collected data.

Response: The post-processed data will be visually investigated whether all the procedures were properly applied. Outliers will be also detected during this investigation.

20.0 Confidentiality*

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

20.1 A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) ***and*** *electronic files.*

Response: The file linking subjects' names to code will be in paper form and will be stored in a locked file cabinet inside PI's laboratory along with signed consent forms. The rest of the data will be stored in a password-protected computer in Furnas 809 which does not have an internet connection. Password will be disclosed only to individuals who are related to this project. After the mandatory 3 years of data retention, the questionnaire will be shredded. Only coded data will be reported in research papers, conference presentations, and participating research lab meetings.

20.2 A. How long will the data be stored?

Response: The file linking subjects' name to ID will be retained until the end of the study. It will be destroyed afterward. All data will be stored for at least 3 years in a password-protected folder regarding this project. After the mandatory 3 years of data retention, the data can be deleted from the password protected computer in Furnas 809

20.3 A. Who will have access to the data?

Response: Only researchers directly involved in the study will have access to this data. Access will only be available to those working on the project through password protection.

20.4 A. Who is responsible for receipt or transmission of the data?

Response: Only the PI (Dr. Jiyeon Kang) will be responsible for receipt or transmission of the data.

20.5 A. How will the data be transported?

Response: If data is transported, a password-protected hard drive will be used.

B. Confidentiality of Study Specimens

Describe the local procedures for maintenance of confidentiality of ***study specimens****.*

☒ **N/A:** No specimens will be collected or analyzed in this research. *(Skip to Section 19.0)*

20.6 B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

20.7 B. How long will the specimens be stored?

Response:

20.8 B. Who will have access to the specimens?

Response:

20.9 B. Who is responsible for receipt or transmission of the specimens?

Response:

20.10 B. How will the specimens be transported?

Response:

21.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

21.1 Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response: There will be extra personal in addition to the operator of the device to ensure the participant's safety. We will collect the response of the Borg exertion scale and ask the participants if there is any adverse effect after each session. A licensed physical therapist will monitor the participants walking patterns.

21.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response: For each week, the cable tension data will be monitored to ensure the proper operation of the device. Safety harness will be also tested before each operation.

21.3 Describe any safety endpoints.

Response: For each training session, researchers are asked to record any adverse effects electronically.

21.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response: We will ask the participants for any adverse effect/Borg exertion scale and all information will be recorded in a daily report form. And the cable tension data will be automatically saved in the computer that is controlling the device. Furthermore, the PI will have a weekly meeting with the team members to check for any adverse effects.

21.5 Describe the frequency of safety data collection.

Response: The cable tension data will be collected for every trial. Borg scale will be asked for every 10 minutes.

21.6 Describe who will review the safety data.

Response: PI will review the safety data by having a periodic meeting with the researcher.

21.7 Describe the frequency or periodicity of review of cumulative safety data.

Response: N/A

21.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response: N/A

21.9 Describe any conditions that trigger an immediate suspension of the research.

Response: N/A

22.0 Withdrawal of Subjects*

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*22.1 Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response: If the participant has difficulties walking for 6 minutes, we will automatically withdraw the participant as 6-min walk is included in one of our metrics. Though highly unlikely, if the participant cannot follow simple instructions to walk and stop he or she may be withdrawn from the study.

22.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response: The PI will inform the participant of early termination. The participant will be compensated for the hours that he/she participated in the study.

22.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response: We destroy all the data and records related to the specific participant whom we withdraw from the study.

23.0 Risks to Subjects*

23.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response: This research involves minimal risk to participants. Subjects will be explicitly informed the following "Some risks are unknown, so if you have experienced any shortness of breath or chest pain in the past while walking, you should not participate in this study." Though highly unlikely, there can be fatigue by repeated walking tasks multiple times. If this is the case, the participant can request a break as much as he/she needs. Also attaching sEMG electrodes on the skin can cause mild skin irritation. Once the participant expresses discomfort, we will stop the experiment and remove the device.

23.2 Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response: Researchers who will perform this study will be trained to ask the participant if the participant feels fatigued every 10 minutes. There will be multiple emergency switches to stop the device immediately. The participant will wear a safety harness when walking with the cable-actuated robotic device.

*23.3 If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response: We do not expect any risk in this experimental procedure.

23.4 If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response: We do not expect any risk in this experimental procedure.

23.5 If applicable, describe risks to others who are not subjects.

Response: We do not expect any risk in this experimental procedure.

24.0 Potential Benefits to Subjects*

24.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response: Our previous study with a cable-actuated system showed that cerebral palsy children showed increased walking ability in step length, walking speed, or single stance time [1]. We expect to see similar benefits in adults with cerebral palsy.

[1] J. Kang, D. Martelli, V. Vashista, I. Martinez-Hernandez, H. Kim, and S. K. Agrawal, "Robot-driven downward pelvic pull to improve crouch gait in children with cerebral palsy," Sci. Robot., 2017, doi: 10.1126/scirobotics.aan2634.

25.0 Compensation for Research-Related Injury

☒ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

*25.1 **If the research procedures carry a risk of research related injury,** describe the available compensation to subjects in the event that such injury should occur.*

Response:

25.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

*NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with **different language regarding research related injury**, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

26.0 Economic Burden to Subjects

26.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response: There will be no cost that subjects will be responsible for because of participation in the research.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

27.0 Compensation for Participation

27.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response: The participant will be compensated for $20/hour. They will be compensated via cash at the end of each session before the participants leave the lab.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

28.0 Consent Process

28.1 Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 27.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*

☐ ***No*** *(If no, Skip to Section 27.0)*

28.2 Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response: The consent form is obtained by PI or researchers in the laboratory located in 809 Furnas Hall or 115 Kimball.

28.3 Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-030)" Sections 5.5 and 5.6.

Response: The participant will be informed before the consent that he or she can use as much time as he/she needs. Participants will be also informed to be allowed to ask questions or withdraw the study when she or he felt discomfort during the study.

28.4 Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response: We will provide compensation of $20/hr to the participants to encourage continuation of this study.

28.5 Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-030)." Pay particular attention to Sections 5.4-5.9. If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

- *The role of the individuals listed in the application who are involved in the consent process*
- *The time that will be devoted to the consent discussion*
- *Steps that will be taken to minimize the possibility of coercion or undue influence*
- *Steps that will be taken to ensure the subjects' understanding*

Response:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-030)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects.
(Skip to Section 26.8)

28.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 6.4 of this protocol.

Response:

28.7 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-030)."

Response:

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 26.9)

28.8 Describe the process to determine whether an individual is capable of consent.

Response:

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 26.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 26.9 and 26.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 26.11 and 26.12).*

28.9 Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response:

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

28.10 ***For research conducted outside of New York State****, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

28.11 Describe the process for ***assent of the adults****:*

- *Indicate whether assent will be obtained from all, some, or none of the subjects.* ***If some, indicate which adults will be required to assent and which will not.***

Response:

- ***If assent will not be obtained from some or all subjects, provide an explanation of why not.***

Response:

28.12 Describe whether ***assent of the adult*** *subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response:

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☒ **N/A**: This study will not enroll subjects who are not yet adults. *(Skip to Section 27.0)*

*28.13 Describe the criteria that will be used to determine **whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research** under the applicable law of the jurisdiction in which the research will be conducted **(e.g., individuals under the age of 18 years)**. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response:

*28.14**For research conducted outside of New York State**, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

28.15 Describe whether parental permission will be obtained from:

Response:

☐ 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.

☐ 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.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

*28.16Describe whether permission will be obtained from individuals **other than parents**, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response:

*28.17 Indicate whether assent will be obtained from all, some, or none of the **children**. If assent will be obtained from some children, indicate which children will be required to assent.*

Response:

28.18 When assent of children is obtained, describe how it will be documented.

Response:

29.0 Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☒ **N/A:** A waiver or alteration of consent is not being requested.

29.1 If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response:

29.2 If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

30.0 Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 29.0)

30.1 Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred

to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).

Response:

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

31.0 Multi-Site Research (Multisite/Multicenter Only)*

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

31.1 Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response:

*31.2 If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as the following. See "WORKSHEET: Communication and Responsibilities (HRP-830).":*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately in accordance with applicable federal regulations and local laws.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response:

31.3 Describe the method for communicating to engaged participating sites (see "WORKSHEET: Communication and Responsibilities (HRP-830)"):

- *Problems (inclusive of reportable events)*
- *Interim results*
- *Study closure*

Response:

*31.4 If this is a multicenter study **where you are a participating site/investigator**, describe the local procedures for maintenance of confidentiality. (See "WORKSHEET: Communication and Responsibilities (HRP-830).")*

- *Where and how data or specimens will be stored locally?*
- *How long the data or specimens will be stored locally?*
- *Who will have access to the data or specimens locally?*
- *Who is responsible for receipt or transmission of the data or specimens locally?*
- *How data and specimens will be transported locally?*

Response:

31.5 If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described elsewheres in the protocol.

- *Describe when, where, and how potential subjects will be recruited.*
- *Describe the methods that will be used to identify potential subjects.*
- *Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*

Response:

32.0 Banking Data or Specimens for Future Use*

☐ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*32.1 If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

Response: Data will be stored in a password-protected desktop computer in the AWEAR laboratory (Furnas Hall Room 809). It will be stored for additional three years after the analysis and only researchers listed in the present IRB will have access to identifiable private information. Individuals who are not on this IRB should get permission from PI and only the data without identifiable private information will be provided.

32.2 List the data to be stored or associated with each specimen.

Response: motion capture, surface EMG data, ground reaction force, shoe insole data, and instrumented treadmill data.

32.3 Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response: If identifiers are removed from identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without additional informed consent. Motion capture data, surface EMG data, ground reaction force data, and shoe insole data will be provided as a text file format. The data will be shared by password protected external hard drive.