HUMAN SUBJECTS PROTOCOL
University of Delaware

Protocol Title: **Optimizing the adaptive treadmill controller**

Principal Investigator
Name: Jane Doe
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Advisor (if student PI):
Name:
Contact Phone Number:
Email Address:

Other Investigators:

Investigator Assurance:

By submitting this protocol, I acknowledge that this project will be conducted in strict accordance with the procedures described. I will not make any modifications to this protocol without prior approval by the IRB. Should any unanticipated problems involving risk to subjects occur during this project, including breaches of guaranteed confidentiality or departures from any procedures specified in approved study documents, I will report such events to the Chair, Institutional Review Board immediately.

1. **Is this project externally funded?** ☐ YES **X** NO

If so, please list the funding source:

2. Research Site(s)

X University of Delaware

☐ Other (please list external study sites)

Is UD the study lead? **X** YES ☐ NO (If no, list the institution that is serving as the study lead)

3. **Project Staff**
Please list all personnel, including students, who will be working with human subjects on this protocol (insert additional rows as needed):

NAME	ROLE	HS TRAINING COMPLETE?
Jane Doe	PI	Yes
Researcher 1	Grad RA	Yes
Researcher 2	Grad RA	Yes
Researcher 3	Undergrad RA	Yes

4. **Special Populations**
Does this project involve any of the following:

Research on Children? NO

Research with Prisoners? NO

If yes, complete the Prisoners in Research Form and upload to IRBNet as supporting documentation

Research with Pregnant Women? NO

Research with any other vulnerable population (e.g. cognitively impaired, economically disadvantaged, etc.)? please describe NO

5. **RESEARCH ABSTRACT** Please provide a brief description in LAY language (understandable to an 8th grade student) of the aims of this project.

Treadmill based therapies have proven to be effective means of increasing walking speed after stroke and other conditions. Increased walking speed is associated with increased propulsive forces applied from the foot to the floor. We have developed an innovative solution that solicits treadmill walking using an adaptive, user-driven control algorithm. This software control strategy uses the user's push-off force and foot position on the treadmill to adjust walking speed. The purpose of this study is to determine how healthy individuals respond to changes in the control algorithm (e.g. emphasizing forces more and position less).

6. **PROCEDURES** Describe all procedures involving human subjects for this protocol. Include copies of all surveys and research measures.

Protocol Summary:
Before each session, all lab equipment, including the fall harness, will be evaluated by trained members of the research team to ensure the safety of all participants. For each session, subjects will be asked to wear shorts, t-shirt and comfortable walking shoes. Potential subjects will be asked to complete a physical activity readiness questionnaire (PAR-Q) to determine eligibility. We will measure subjects' weight and height. Age and sex will also be recorded. Subjects' walking speed over ground will be measured to give us an idea of subjects' walking ability. Subjects will be asked to walk on a treadmill at a variety of speeds ranging from subjects' slowest to subjects fastest walking speed. The subject's fastest walking speed will be used to determine maximum speed for a real-time adaptive treadmill speed controller.

Reflective markers will be attached to the subject's legs and upper body using Velcro straps. Elastic bands will be wrapped around subjects' thighs, calves and pelvis and small reflective balls will be attached. These balls will also be taped to subjects' sneakers and on subjects' upper back, shoulder, hip, knee, and ankle joints with adhesive skin tape. Electromyographic (EMG) electrodes, used to measure muscle activity, will also be attached to the subjects' thighs and calves with adhesive skin tape. If there is an allergy to the tape, non-irritating skin tape or non-tape attachments will be used. The movement of subjects' legs and upper body will be recorded using special video cameras which detect reflective objects attached to subjects' body segments. We may also collect video for comparison with the motion data (if consent is provided).

Subjects will complete a total of fifteen, one-minute walking trials on a treadmill in the adaptive mode at their self-selected speeds. The adaptive controller software will be used to smoothly and safely adjust the speed of the treadmill in response to how hard the subject is pushing, step length, and body position on the treadmill. In each trial, the ratio of sensitivity of treadmill belt speed to push-off force and step length will be varied to modify how easily subjects achieve their preferred speed. The subject will be asked to rest at least 1 to 2 minutes between each trial. Conditions will be presented in random order. After each trial, subjects will be asked to respond to a survey (see attachment).

Subjects will also be asked to walk for 10 minutes on the adaptive treadmill at their self-selected comfortable speed. Total walking time will not exceed one hour.

Total time: Setup will take approximately 30 min, the testing session will take approximately 1 hour, and the total time for subjects participation will be no longer than 1.5 hours. Testing will be conducted in the Neuromuscular Biomechanics Laboratory in the STAR Health Sciences Complex building at the University of Delaware.

7. **STUDY POPULATION AND RECRUITMENT**
Describe who and how many subjects will be invited to participate. Include age, gender and other pertinent information.
40 healthy men and women between the ages of 18-45 with no history of muscle, bone or nervous system disorders will participate in this study. The healthy subjects will be recruited from the University of Delaware community. Any participant may withdraw from the study at any time.

Attach all recruitment fliers, letters, or other recruitment materials to be used. If verbal recruitment will be used, please attach a script.
Subjects will be recruited in the classroom and by word of mouth. We will ask "If you would like to participate in a study which involves walking on an adaptive treadmill for rehabilitation applications, please contact Dr. Jane Doe at Jdoe@udel.edu."

Describe what exclusionary criteria, if any will be applied.
Potential subjects will be asked to complete a physical activity readiness questionnaire (PAR-Q). Subjects will be excluded if they give an affirmative answer to questions 1, 2, 3, 4 or 9 or give more than one affirmative answer to questions 5, 6, 7 or 8 on the PAR-Q. Individuals with significant cardiopulmonary or vascular conditions will not be permitted to enroll. In addition, we will estimate the subject's body mass index which is a measure of body fat and must be less than 30 for the subject to participate. Individuals older than 45 years of age will also be excluded.

Describe what (if any) conditions will result in PI termination of subject participation.
None

8. **RISKS AND BENEFITS**
List all potential physical, psychological, social, financial or legal risks to subjects (risks listed here should be included on the consent form).
The possible risks associated with this study will include falling, fatigue, and joint soreness. Injuries such as muscle strains and tears are possible, but unlikely. If they so choose, subjects may wear a safety harness during treadmill testing that can prevent a fall to the ground should they lose their balance. Also, at any time during testing, if needed, the experimenter can push a safety switch that will stop the treadmill belt immediately.

In your opinion, are risks listed above minimal* or more than minimal? If more than minimal, please justify why risks are reasonable in relation to anticipated direct or future benefits.

Risks are minimal

*(*Minimal risk means 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)*

What steps will be taken to minimize risks?

We have taken great care to reduce the risks associated with walking on the treadmill. We see minimal risk of confidentiality—data are coded and no identifying information is used in any analyses or publication. We adhere to all HIPAA privacy rules that affect research protocols.

Risks related to recording motion capture and EMG: Markers, EMG electrodes, and adhesives sometimes cause skin irritation in individuals with sensitive skin. We will minimize this risk by utilizing as little adhesive as possible and by placing position markers over clothing rather than skin whenever possible. If irritation does occur, it is expected to resolve within 12-24 hours.

Any incidents involving injury to study subjects will be presented to research team members and the

IRB immediately. The subject's current status is discussed as well as procedures to minimize any future subject risk.

Describe any potential direct benefits to participants.
There are no direct benefits to participants.

Describe any potential future benefits to this class of participants, others, or society.
This study will create a new and thorough set of information that can be used by researchers and clinicians to develop future therapies that incorporate real time feedback.

If there is a Data Monitoring Committee (DMC) in place for this project, please describe when and how often it meets.

No

9. **COMPENSATION**
Will participants be compensated for participation?
No

If so, please include details.

10. **DATA**
Will subjects be anonymous to the researcher?
No

If subjects are identifiable, will their identities be kept confidential? (If yes, please specify how)
The data will be collected in a manner that subjects are identified indirectly through identifying codes linked to the subjects. This code number will be used in all computer files where the data will be entered such as excel and statistics programs. Consent forms will be stored in a locked filing cabinet in the laboratory.

How will data be stored and kept secure (specify data storage plans for both paper and electronic files. For guidance see http://www.udel.edu/research/preparing/datastorage.html)
A database containing subject numbers, demographic information, and collected data will be stored on a password protected server only accessible to members of the research team. The data will be reported in a manner that subjects are NOT identified directly or indirectly through identifying information. Identifying information will be kept only in a single file, encrypted and stored on a password protected server. This file will contain the link between subject codes and identifying information.

How long will data be stored?
Data collected from completion of the Par-Q questionnaire will be recorded in writing on forms used expressly for this purpose without participant-identifiable information. These written forms will be stored in a locked filing cabinet for an indeterminate period of time. Data from motion analysis testing will be stored on a university-owned computer that requires password access. Again, this data will not contain any identifiable information. Upon study completion the link between subject codes and

identifying information will be destroyed.

Will data be destroyed? ☐ YES **X** NO (if yes, please specify how the data will be destroyed)

Will the data be shared with anyone outside of the research team? ☐ YES X NO (if yes, please list the person(s), organization(s) and/or institution(s) and specify plans for secure data transfer)

How will data be analyzed and reported?
Data will be analyzed using Cortex, Visual 3D, Microsoft Excel, Labview, OpenSim, and Matlab software on laboratory computers.

11. **CONFIDENTIALITY**
Will participants be audiotaped, photographed or videotaped during this study?
Video recordings and photographs may be obtained with subject consent for research purposes. If the subject does not consent, they will not be eliminated from participation in the study.

How will subject identity be protected?
Any computer files containing information that could identify the subject will be password protected. Data will be identified by the use of a subject number only and will be stored on a password-protected server.

Is there a Certificate of Confidentiality in place for this project? (If so, please provide a copy).
No

12. **CONFLICT OF INTEREST**
(For information on disclosure reporting see: http://www.udel.edu/research/preparing/conflict.html)

Do you have a current conflict of interest disclosure form on file through UD Web forms? YES

Does this project involve a potential conflict of interest*? NO

* As defined in the University of Delaware's Policies and Procedures ,a potential conflict of interest (COI) occurs when there is a divergence between an individual's private interests and his or her professional obligations, such that an independent observer might reasonably question whether the individual's professional judgment, commitment, actions, or decisions could be influenced by considerations of personal gain, financial or otherwise.

If yes, please describe the nature of the interest:

13. **CONSENT and ASSENT**

_X___ Consent forms will be used and are attached for review (see Consent Template under Forms and Templates in IRBNet)

____ Additionally, child assent forms will be used and are attached.

____ Waiver of Documentation of Consent (attach a consent script/information sheet with the signature block removed).

____ Waiver of Consent (Justify request for waiver)

14. **Other IRB Approval**
Has this protocol been submitted to any other IRBs?
NO

If so, please list along with protocol title, number, and expiration date.

15. **Supporting Documentation**
Please list all additional documents uploaded to IRBNet in support of this application.

Consent form (clean and tracked)
Modified PARQ
Survey