INSTITUTIONAL REVIEW BOARD

AUTHORIZATION AGREEMENT

FOR COLLABORATIVE RESEARCH

Reviewing Institution (i.e., institution providing IRB review)

Institution Name: *University of Delaware*
FWA #: FWA00004379
IRB Registration #: IRB00000472

Relying Institution (i.e., institution relying on the review of the above-designated IRB)

Institution Name: *Virginia Polytechnic Institute and State University*
FWA #: *FWA00000572*

Pursuant to 45 CFR 46.114, the above-listed institutions are entering into this agreement for the *Reviewing Institution* to conduct Institutional Review Board (IRB) review and oversight activities of the collaborative human subject research activities identified below on behalf of the *Relying Institution*. The review performed by the *Reviewing Institution's* IRB will meet the human subject protection requirements of the *Relying Institution's* OHRP-approved Federalwide Assurance, and include a description of the research to be conducted by the *Relying Institution*.

This agreement covers the following activities:

☐ All human subject research conducted in collaboration with Virginia Tech, **or**

x The following specific human subject research protocol(s):

Research Protocol Title: [1110233-1] Smart Wearable Systems to Support and Measure Movement in Individuals With and Without Mobility Impairments
Principal Investigator: Lucy Dunne (University of Minnesota)
Other Investigators: Michele Lobo (UD), Mark Jones and Tom Martin (VT)
Sponsoring Agency: NSF (NSF Smart and Connected Health Program)

The *Reviewing Institution's* IRB agrees to the following with regard to the above-listed research protocol(s) or activities:

I. Provide initial and continuing review in accordance with 45 CFR 46 and its FWA.
II. Arrange for prompt reporting to the *Relying Institution's* IRB of any of the following, as defined and determined by the *Reviewing Institution's* IRB:
    a. Any unanticipated injuries or problems involving risks to subjects or others.
    b. Any serious or continuing non-compliance.
    c. Any suspension or termination of IRB approval.
III. Provide relevant minutes of IRB meetings and protocol documents to the *Relying Institution* upon request.

The *Relying Institution* is responsible for the timely compliance of its employees, students, and agents with the *Reviewing Institution* / IRB's policies, procedures, and determinations.

This document must be signed and dated by Institutional Officials (IO) at both institutions, kept on file at both institutions, and provided to the Office for Human Research Protections upon request.

Signature of IO at *Reviewing Institution*:

Charles G. Riordan Date: 9/11/17

Name: Charles G. Riordan
Title: Vice President for Research, Scholarship, and Innovation
Email: riordan@udel.edu

Signature of IO at *Relying Institution*:

_____ Date: _____

Name: Dr. Theresa Mayer
Title: VP for Research and Innovation
Email: tsmayer@vt.edu

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This agreement covers the following activities:

All human subject research conducted in collaboration with Virginia Tech, **or**

x The following specific human subject research protocol(s):

Research Protocol Title:	[1110233-1] Smart Wearable Systems to Support and Measure Movement in Individuals With and Without Mobility Impairments
Principal Investigator:	Lucy Dunne (University of Minnesota)
Other Investigators:	Michele Lobo (UD), Mark Jones and Tom Martin (VT)
Sponsoring Agency:	NSF (NSF Smart and Connected Health Program)

The *Reviewing Institution's* IRB agrees to the following with regard to the above-listed research protocol(s) or activities:

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    a. Any unanticipated injuries or problems involving risks to subjects or others.
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This document must be signed and dated by Institutional Officials (IO) at both institutions, kept on file at both institutions, and provided to the Office for Human Research Protections upon request.

Signature of IO at *Reviewing Institution*:

Date:

Name: Charles G. Riordan
Title: Vice President for Research, Scholarship, and Innovation
Email: riordan@udel.edu

Signature of IO at *Relying Institution*:

Date: 9/17/2017

Name: Dr. Theresa Mayer
Title: VP for Research and Innovation
Email: tsmayer@vt.edu

Institutional Review Board
210H Hullihen Hall
Newark, DE 19716
Phone: 302-831-2137
Fax: 302-831-2828

DATE:	August 13, 2020
TO:	Michele Lobo, PT, PhD
FROM:	University of Delaware IRB
STUDY TITLE:	[1110233-4] Smart Wearable Systems to Support and Measure Movement in Individuals With and Without Mobility Impairments
SUBMISSION TYPE:	Continuing Review/Progress Report
ACTION:	APPROVED
APPROVAL DATE:	August 13, 2020
EXPIRATION DATE:	August 15, 2021
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # *(9)*

Thank you for your Continuing Review/Progress Report submission to the University of Delaware Institutional Review Board (UD IRB). The UD IRB has reviewed and APPROVED the proposed research and submitted documents via Expedited Review in compliance with the pertinent federal regulations.

Please continue to reference https://research.udel.edu/coronavirus for the most up-to-date recommendations regarding in-person research interaction with subjects during the COVID-19 national emergency.

As the Principal Investigator for this study, you are responsible for and agree that:

- All research must be conducted in accordance with the protocol and all other study forms as approved in this submission. Any revisions to the approved study procedures or documents must be reviewed and approved by the IRB prior to their implementation. Please use the UD amendment form to request the review of any changes to approved study procedures or documents.
- Informed consent is a process that must allow prospective participants sufficient opportunity to discuss and consider whether to participate. IRB-approved and stamped consent documents must be used when enrolling participants and a written copy shall be given to the person signing the informed consent form.
- Unanticipated problems, serious adverse events involving risk to participants, and all non-compliance issues must be reported to this office in a timely fashion according with the UD requirements for reportable events. All sponsor reporting requirements must also be followed.

Oversight of this study by the UD IRB REQUIRES the submission of a CONTINUING REVIEW seeking the renewal of this IRB approval, which will expire on August 15, 2021. A continuing review/progress report form and up-to-date copies of the protocol form and all other approved study materials must be submitted to the UD IRB at least 45 days prior to the expiration date to allow for the required IRB review of that report.

If you have any questions, please contact the UD IRB Office at (302) 831-2137 or via email at hsrb-research@udel.edu. Please include the study title and reference number in all correspondence with this office.

HUMAN SUBJECTS PROTOCOL
University of Delaware

Protocol Title: Smart Wearable Systems to Support and Measure Movement in Individuals With and Without Mobility Impairments

Principal Investigator
Name: Michele A. Lobo
Department/Center: Physical Therapy
Contact Phone Number: 302-831-8526
Email Address: malobo@udel.edu

Advisor (if student PI):
Name:
Contact Phone Number:
Email Address:

Other Investigators:
Lucy Dunne, PhD
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Brad Holschuh, PhD
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Thomas Martin, PhD
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Professor & Bradley Faculty fellow of Education
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tlmartin@vt.edu

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?** **X** YES ☐ NO

If so, please list the funding source: This project is funded through the NSF Smart and Connected Health Program. SCH: INT: Collaborative Research: Smart Wearable Systems to Support and Measure Movement in Children With and Without Mobility Impairments.

2. Research Site(s)

X University of Delaware

X Other (please list external study sites)

This is a multi-site project involving investigators at UD, the University of Minnesota (UM), and Virginia Tech (VT). Lucy Dunne at UM is the PI on the grant. The other investigators listed above are co-PIs. Most human subjects data collection will happen at UD so we are requesting UD be the IRB of record for the project.

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?
Andrea Cunha	Post-doctoral researcher	Yes
Michele Lobo	Investigator	Yes
Lucy Dunne	Investigator	Yes
Brad Holschuh	Investigator	Yes
Tom Martin	Investigator	Yes
Mark Jones	Investigator	Yes
Bai Li	Graduate Student	Yes

Julie Orlando	Graduate Student	Yes
Zainab Saleh A Alghamdi	Graduate Student	Yes
Amanda Redhouse	Graduate Student	Yes

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

Research on Children? yes

Research with Prisoners? no

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

Research with Pregnant Women? Pregnant women may participate in this study as long as they can fit in typically sized clothing. Maternity garments will not be made for this study. There are no special risks associated with being pregnant in this study so we will not screen for pregnancy. Participants will be informed that those wearing maternity clothing may not participate in this study at the time of consent.

Research with any other vulnerable population (e.g. cognitively impaired, economically disadvantaged, etc.)? please describe

Individuals with motor and cognitive disabilities who can engage in the protocol are welcome to participate.
For Aim 1, adults providing consent to participate in the study should be typical adults who demonstrate the ability to read, understand, and sign the consent.

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

This project focuses on the development of wearable technologies to measure and support arm mobility for individuals with mobility impairments. Because arm mobility is important for daily activities like eating and self care, it is important both to develop assistive technologies to help people overcome these impairments and to be able to measure the effect of interventions and technologies on everyday movements across time. Most existing assistive and sensing technologies are bulky, uncomfortable, unattractive, and can only be used in lab or medical environments.

Our interdisciplinary team from fashion & apparel design, aerospace engineering, computer and electrical engineering, and rehabilitation will develop safe, soft, low profile sensing and assistive technologies that look and feel like everyday clothing. We will aim to: 1) test how effectively a garment with thread sensors stitched to look and feel like typical seams measures movement and activity for people 3-30 years old with typical movement abilities; 2) test whether daily use of a low-tech soft inflatable arm support garment impacts arm function across time for children 3-14 years old with arm movement impairments, using the sensors from the first aim to track garment use and activity; and 3) develop and test a soft garment that combines inflatable components and shape-memory fibers to support arm movement for children 3-14 years old with arm movement impairments. Data from the sensors will be processed in a manner that will allow for movement information (amount and amplitude) and activity information (reaching, combing hair, eating, for example) for participants irrespective of body shape and movement of the garment on the body. This work will contribute to the development of technologies that enable understanding and effects of interventions on mobility impairments in natural contexts, as well as the growing smart textiles and clothing industry in the USA.

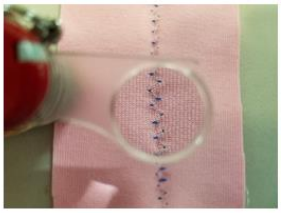
6. **PROCEDURES** Describe all procedures involving human subjects for this protocol. Include copies of all surveys and research measures.

This project has 3 aims, the procedures for which are described below. Each aim will have its own consent and assent forms as well as its own independent participant pool. The figure below shows the timeline for data collection for the three aims.

Informed consent and assent forms will be reviewed with parents and children and signed prior to participation in the activities described below. Parental consent will be sought for children 3-6 years old. We will also review the study procedures with 3-6 year olds using the attached script and images. Parental consent and child assent will be sought for children 7 years and older. When working with younger populations who cannot yet read well, we will explain our planned activities in a developmentally appropriate manner throughout the study and will not engage in activities with children who verbally or behaviorally (via facial expressions, vocalizations) express a lack of desire to participate.

When questionnaires are used, they will be provided to families during visits and can be completed during or after visits. Typically, parents complete these on their own but if parents prefer, experimenters can read and talk through them.

<u>Aim 1: Test how effectively a garment with thread sensors stitched to look and feel like typical seams measures movement and activity for people 3-30 years old with typical movement</u>



In an earlier NSF funded project, PIs Dunne, Jones, and Martin developed a garment with stitched conductive thread sensors (see figure to the right). The sensors look and feel like typical thread seams (see figure to the left). These sensors provide information regarding stretch and bend. By placing the sensors strategically across joints, they can provide information about joint movement (amount and amplitude). By placing redundant sensors across joints, garments can be made to be loose fitting and comfortable while still providing accurate movement information. By placing separate sensors across multiple joints, algorithms can be created to categorize the activity of users. In Dunne, Jones, and Martin's previous project, they showed these sensors perform equally to electrogoniometers. They were also able to use these sensors in garments to distinguish pathological joint-movement characteristics such as valgus knee bending from healthy movement. They also developed algorithms for movement and activity data that were independent of user's body size (and therefore did not require user dependent calibration) and type of sensor used to gather data. They bench tested this garment on stationary mannequins and then on moving humanoid mannequins and finally on human users. Conductive thread is widely available for hobbyists and has been used in a variety of wearable DIY projects (e.g. https://www.pinterest.com/pin/434949276485496712/) and commercial products. For example, this thread has been used in hats and clothing to allow them to light up. It has also been used in fencing garments for years. The "scoring area" is conductive to register contact with the opponent's metal sword. Microcontrollers integrated within garments can allow for information from conductive thread sensors to be stored for future analysis or sent via Bluetooth for immediate feedback. Data from the sensors are gathered by microprocessors powered by batteries integrated in the garment (see figure to the left). Data are time stamped and either sent to a research computer via wifi or Bluetooth during data collections or stored on memory cards in the microprocessors for future transfer to a lab computer.

The current project will expand Dunne and Martin's work to determine the validity and reliability of these textile sensors for measuring movement and classifying activity for younger individuals. UM will lead design and fabrication of the garment in collaboration with other sites and users. UD will lead data collection and analysis of video data. VT will lead sensor data analysis from traditional motion capture and textile sensors.

Time commitment for the project: 4 visits total, a 20-30 minute initial visit followed by 3, 30-60-minute data collections at a location convenient to families

Fifty participants 3-30 years old will be recruited from the Early Learning Center at UD (under the direction of their research coordinator) and from the community. A flyer and on-line posting of flyer content will be used to recruit participants (see attached). To be included, participants (or parents of child participants) will need to complete a health and demographic questionnaire (10 minutes; attached) reporting no movement impairments or restrictions that would limit study participation. In addition, participants should have full active range of motion across all major joints in their arms, trunk, and legs. Participants will initially be measured according to the attached measurement guide, their height and weight will be measured, and we will ask their current clothing size in order to determine the proper size for the sensor garment. Garments will either be custom made for individual participants or will be laundered between data collections. We will aim to collect all of this information in one brief visit (20-30 minutes including health and demographic questionnaire). This meeting can occur in person or via video meeting with participants or parents of participants performing measurements with our guidance, whichever is most convenient for participants.

Once the proper size garment is available, participants will engage in three assessments while wearing the garment. All assessments will be video recorded. An already validated method of motion analysis (e.g. TrakSTAR Motion Analysis or video analysis like Kinovea) will be also be utilized. The assessments are:

1) Static Movement Assessment I (about 5 minutes): Imitation of static postures demonstrated by the experimenter (e.g. bending the elbows 90° and holding for 3 seconds) to compare static joint angle measurements between the garment sensors and the already validated motion analysis method.
2) Active Movement Assessment I (about 5 minutes): Imitation of movement sequences demonstrated by the experimenter (e.g. bending the elbow and straightening it in pace with a metronome) to compare dynamic joint angles between the garment sensors and the already validated motion analysis method.
3) Functional Activity Assessment (about 10-25 minutes): Engaging in typical functional activities such as reaching, bimanual activity, and eating.

At the first data collection, these 3 assessments will be performed and then the 1st and 2nd assessments will be repeated. The visit will last about 30-60 minutes. Comparing data from the first to the second Static and Active Movement Assessments will allow us to determine the reliability of the sensor garment within a wearing session. Comparing data between the sensor garment and the already validated motion analysis method throughout all assessments will allow us to determine the validity of the movement data from the sensor garment. Comparing activity data calculated from our algorithms and from video coding during the Functional Activity Assessment will allow us to determine the validity of the activity data from the sensor garment.

In order to determine the reliability of the sensor garment across time, we will repeat this same procedure at a second visit separated from the first by at least one day.

Participants and parent of child participants will also be asked to complete a questionnaire (10 minutes; attached) regarding their perceptions of the sensor garment related to look, fit, and feel.

In order to gather data about movement and activity when arm movement is limited for people with typical movement abilities, we will repeat the procedure one more time at a third visit with the participant wearing the garment now with components that will make arm movement more challenging (see figure to the right). These components will apply soft forces against lifting of the arm. Soft, adjustable, elastic bands can help simulate arm weakness by making it more difficult to lift the arm against gravity. Gathering these data will help us to start to create algorithms that may work for Aim 2 that includes children whose arm movements are impaired.

ROLES:

- UM will lead the team in the garment design and fabrication process
- UD will lead the team in the recruitment and data collection processes
- VT will lead the team in sensor and motion data analysis and algorithm development and testing

<u>Aim 2: Test whether daily use of a low-tech soft inflatable arm support garment impacts arm function across time for children 3-14 years old with arm movement impairments, using the sensors from the first aim to track movement and activity across time.</u>

Exoskeletons are devices that can be worn to enhance performance or assist movement. Co-PI Lobo has experience working with two available exoskeletons, the P-WREX from Nemours and the Playskin Lift exoskeletal garment developed by Lobo's team. Lobo has ongoing projects with the Playskin Lift that involve testing with infants and toddlers with arm movement impairments. The Playksin Lift is the first exoskeletal garment or rehabilitation. It is a comfortable, soft shirt or onesie with vinyl tunnels under each arm where bundles of wire can be inserted to act as springs that provide upward lift to the child's arms. Lobo's work has shown this garment is feasible to use, improves function within sessions, and may improve performance across time if used daily for intervention.

In Aim 2, we will test the feasibility and efficacy of a more recent version of the Playskin, the Playskin Air (see figure below; please note we have parental approval for use of this image for all project documents). Instead of metal springs, this garment uses air bladders, much like those in life jackets, to provide lift to the arms. A nice quality about air bladders is that they can allow for the development of more precise mechanisms for user control (Aim 3 in this project). Another nice quality is that while inflatable bladders can support the arms, they do not resist movement against them and in other directions as can also be seen in the figure. The version of the Playskin Air used for this aim will be a low-tech version that does not require high-tech textile-based control

mechanisms. It can be inflated using an external pump or oral inflation (like blowing up a beach ball; see tubing in figure to the left).

Time commitment for the project: 4 visits total, a 1-1.5 hour initial visit followed by 13, weekly 40-60-minute data collections at a location convenient to families

Thirty participants 3-14 years old with arm movement impairments will be recruited from the Early Learning Center at UD (under the direction of their research coordinator) and from the community. A flyer and on-line posting of flyer content will be used to recruit participants (see attached). To be included, participants (or parents of young child participants) will need to complete a health and demographic questionnaire (10 minutes; attached) reporting movement impairments. In addition, participants should demonstrate impaired ability to lift their arms and hold them up against gravity.

Data collection for this study will run for 3 months.

At the start of the study, to describe motor abilities of participants, their motor ability will be assessed using the Bruininks-Oseretsky Test of Motor Proficiency, Second Edition (BOT-2) standardized assessment (attached; 45-60 minute assessment). Their fine motor abilities will also be classified using the Manual Ability Classification System (MACS), their gross motor abilities will be classified using the Gross Motor Function Classification System (GMFCS), and their communication abilities will be classified using the Communication Function Classification System (CFCS; all attached). These are classification systems of ability that will be based on our observations of the children and on parent report. Parents will be asked to complete the Caregiver Priorities & Child Health Index of Life with Disabilities (CPCHILD) Questionnaire (20-30 minutes) to document their perspectives on health status, comfort, well being, and ease of care of their children. Participants will be measured according to the attached measurement guide, their height and weight will be measured, and we will ask their current clothing size in order to determine the proper size for the garment. Two garments, one that incorporates the sensors from Aim 1 and another that incorporates the sensors from Aim 1 with the support of the Playskin Air, will be custom made for individual participants. We will aim to collect this initial information via one visit, more if families prefer (about 1-1.5 hours total).

Once the proper size sensor garment is available, participants will be randomly assigned in blocks of 3 (to ensure assignment is distributed among all conditions) to one of 3 conditions varying in Baseline and Intervention Phase lengths for this multiple baseline single case study (see table below; B=Baseline Phase, I=Intervention Phase, PI=Post-Intervention Phase).

Week:	0	1	2	3	4	5	6	7	8	9	10	11	12
Condition 1	B	B	B	I	I	I	I	I	I	PI	PI	PI	PI
Condition 2	B	B	B	B	I	I	I	I	I	PI	PI	PI	PI
Condition 3	B	B	B	B	B	I	I	I	I	PI	PI	PI	PI

During the Baseline Phase, the assessments will be performed with children wearing the sensor garments. All assessments will be video recorded. An already validated method of motion analysis (e.g. TrakSTAR Motion Analysis or video analysis like Kinovea) will be also be utilized. The assessments will include:

1) Passive Range of Motion Assessment (about 5 minutes): The child's shoulders, elbows, wrists, and fingers will be moved gently to the end of their available range of motion.
2) Active Range of Motion Assessment (about 5 minutes): The child will be asked to actively move through the shoulder, elbow, wrist, and finger ranges of motion as far as possible against gravity and then, if full motion against gravity is not observed, in planes with gravity eliminated.
3) Static Movement Assessment I (about 5 minutes): Imitation of static postures that fall within

the child's active range of motion demonstrated by the experimenter (e.g. bending the elbows 90° and holding for 3 seconds) to compare static joint angle measurements between the garment sensors and the already validated motion analysis method.

4) Active Movement Assessment I (about 5 minutes): Imitation of movement sequences that fall within the child's active range of motion demonstrated by the experimenter (e.g. bending the elbow and straightening it in pace with a metronome) to compare dynamic joint angles between the garment sensors and the already validated motion analysis method.
5) Functional Activity Assessment (about 10-25 minutes): Attempting to engaging in typical functional activities such as reaching, bimanual activity, and eating.

At each Baseline data collection, these assessments will be performed and then the 3rd and 4th assessments will be repeated. The visit will last about 40-60 minutes. Comparing data from the first to the second Static and Active Movement Assessments will allow us to determine the reliability of the sensor garment within a wearing session. Comparing data between the sensor garment and the already validated motion analysis method throughout all assessments will allow us to determine the validity of the movement data from the sensor garment. Comparing activity data calculated from our algorithms and from video coding during the Functional Activity Assessment will allow us to determine the validity of the activity data from the sensor garment. These data will be important to gather because the garment and algorithms may need to be adjusted to correctly identify movements and activities for populations with impaired arm movement. The baseline period will also be important because this study uses a single-case design in which participants will serve as their own controls. The baseline period will allow us to measure changes related to aging, experience, and other time-related factors to determine if changes during the next phase, the Intervention Phase, exceed those. Because assessments will be repeated weekly, we will also have data available to assess reliability of the sensor garment across time. Participants will also be asked to wear the sensor garment for 1-3 hours during times they are active a few times during the week so we can track their typical movement activity. At each assessment, users' reports of sensor garment wear (log attached) will be collected.

At the last Baseline assessment, participants and parents will also be asked to complete a questionnaire (attached) regarding their perceptions of the sensor garment related to look, fit, and feel. The BOT-2 and Caregiver Priorities & Child Health Index of Life with Disabilities (CPCHILD) questionnaire will also be repeated. At this point they will receive their sensor+support garment to transition into the Intervention Phase. They will keep their sensor garment from the Baseline Phase. The Intervention Phase will last 4-6 weeks, during which participants will be asked to engage in typical daily activities while wearing the sensor+support garment or the sensor only garment 1-3 hours per day, aiming for about 4-6 days/week of wear. Assessments will happen every week. The assessments will be the same as those during the Baseline Phase except assessments 3 and 4 will not be repeated as they were in the Baseline Phase. In addition, all assessments will be performed once with the sensor only garment and once with the sensor+support garment with the garment order randomly assigned for each week. At each assessment, users' reports of intervention and garment wear (log attached) will be collected.

At the last Intervention assessment, participants and parents will also be asked to complete a questionnaire (attached) regarding their perceptions of the sensor+support garment related to look, fit, function, and feel. The BOT-2 and Caregiver Priorities & Child Health Index of Life with Disabilities (CPCHILD) questionnaire will also be repeated. At this visit they will transition into the 4-week Post-Intervention Phase. They will keep both garments but will be informed they no longer need to wear the support garment for daily activity for the study. They can use the sensor+support garment (or not) as they desire. They will still be asked to wear the sensor only garment 1-3 hours during typical activity a few times per week. Assessments will occur every week. The assessments will be performed as they were during the Intervention Phase. At each assessment, users' reports of

garment wear (log attached) will be collected.

At the last Post-Intervention assessment, participants and parents will also be asked to repeat the questionnaire (attached) regarding their perceptions of the sensor+support garment related to look, fit, and feel to determine if these have been altered with time and differential use and to seek previously unidentified design needs. The BOT-2 and Caregiver Priorities & Child Health Index of Life with Disabilities (CPCHILD) questionnaire will also be repeated.

ROLES:

- UM will lead the team in the garment design and fabrication process
- UD will lead the team in the recruitment and data collection processes
- VT will lead the team in sensor and motion data analysis and algorithm development and testing

<u>Aim 3: Develop and test a soft garment that combines inflatable components and shape-memory fibers to support arm movement for children 3-14 years old with arm movement impairments.</u>

This aim will begin with bench testing. Once a garment is ready for testing with human subjects for this aim, we will submit an amendment to this protocol to include procedures, assent, consent, and related IRB documents for this aim. No human subjects testing will occur for Aim 3 prior to approval of that amendment.

The exoskeletons currently available to children are passive ones that provide a static level of support rather than varying support based on users' desires. This is a significant problem for older children who want to be independent in determining for instance whether their arms are at their side for walking in the hall, supported at desk height for schoolwork, or supported at head height for grooming activities.

Co-PI Lobo has experience working with engineers at UD to develop and bench test inflatable garments that support arm movement (Playskin Air, Aim 2). Co-PI Holschuh has his PhD in Aerospace Biomedical Engineering from MIT and has experience making a variety of wearable garments (e.g. compression garments, a "Back to the Future Garment" with changing arm length) that incorporate shape-memory alloys (SMAs). These are metals that can assume different shapes based on their temperature. The temperature at which they change shape can be controlled to be within different ranges. For instance, these metals are currently used in orthodontics so that braces no longer need to be regularly tightened but instead use SMA springs that assume a tightened state based on the temperature in the mouth.

For Aim 3, UM will lead the development of a safe, comfortable, aesthetically pleasing, accessible garment that integrates pneumatic and SMA technologies to support the arms of users with movement impairments. UM will work closely with the other sites and with users to develop a garment that meets the broad needs of users.

ROLES:

- UM will lead the team in the garment design and fabrication process
- UD will lead the team in the recruitment and data collection processes
- VT will lead the team in sensor and motion data analysis and algorithm development and testing

7. **STUDY POPULATION AND RECRUITMENT**

Describe who and how many subjects will be invited to participate. Include age, gender and other pertinent information.

Aim 1: Test how effectively a garment with thread sensors stitched to look and feel like typical seams measures movement and activity for people 3-30 years old with typical movement
50 participants, 3-30 years old, without identified movement impairments
Both genders and all races, socioeconomic statuses are welcome
We will aim for approximately 50% males, 50% females and a good distribution of participants across the ages of 3-14 years with some participants 14-30

Aim 2: Test whether daily use of a low-tech soft inflatable arm support garment impacts arm function across time for children 3-14 years old with arm movement impairments, using the sensors from the first aim to track movement and activity across time.
Thirty participants, 3-14 years old, with identified arm movement impairments
Both genders and all races, socioeconomic statuses are welcome
We will aim for approximately 50% males, 50% females and a good distribution of participants across the ages of 3-14 years

Participation in the study is voluntary. During the first contact made with potential participants, written information explaining the study will be provided that explains in simple terms, a) criteria for participation, b) purpose of the research and procedures involved, c) right to withdraw at any time without penalty of any kind, d) assurance of confidentiality (via number representation vs. name), terms of remuneration. If the individual meets the criteria for participation and is interested, the information just described will be reviewed, questions will be answered and an informed consent will be signed in the presence of a witness. Participants will be reminded by the researcher/recruiter that this signature does not bind them to participate and that they are free to withdraw at any time without providing a reason.

Attach all recruitment fliers, letters, or other recruitment materials to be used. If verbal recruitment will be used, please attach a script.
Flyers attached for Aims 1 and 2

Describe what exclusionary criteria, if any will be applied.
Aim 1: Test how effectively a garment with thread sensors stitched to look and feel like typical seams measures movement and activity for people 3-30 years old with typical movement
Individuals will not be invited to participate if they report movement impairments or restrictions, cannot safely and independently engage in the data collection activities, are not available for data collections, if they are wearing maternity clothing, or have any visual or motor impairments that would restrict participation in the activities.

Aim 2: Test whether daily use of a low-tech soft inflatable arm support garment impacts arm function across time for children 3-14 years old with arm movement impairments, using the sensors from the first aim to track movement and activity across time.
Individuals will not be invited to participate if they cannot safely engage in the data collection activities, cannot follow multiple-step directions, do not have an effective means of communicating their comfort level in the garments, do not have the passive range of motion at the shoulder (0-80 degrees flexion) or elbow (0-70 degrees flexion) necessary to wear use the support garment (reported by parents and verified as necessary by a trained post doctoral researcher, PT, or graduate student researcher), are not available for data collections, are not within easy driving distance and do not have access to a video device (e.g. smart phone or computer) for distance communication (e.g. via skype), or have visual or motor impairments that would restrict participation in the activities.

Describe what (if any) conditions will result in PI termination of subject participation.

Aim 1: Test how effectively a garment with thread sensors stitched to look and feel like typical seams measures movement and activity for people 3-30 years old with typical movement
Individuals may be excluded after consenting if new information suggests they have movement restrictions, they cannot safely and independently engage in the data collection activities, they are not available for data collections or it is not possible to match their schedule with that of the experimenters, they have any impairments that would restrict participation in the activities, or they consistently demonstrate negative affect during data collections.

Aim 2: Test whether daily use of a low-tech soft inflatable arm support garment impacts arm function across time for children 3-14 years old with arm movement impairments, using the sensors from the first aim to track movement and activity across time.
Individuals may be excluded after consenting if they cannot safely and fully engage in the data collection activities, they are not available for data collections or it is not possible to match their schedule with that of the experimenters, they develop any impairments that would restrict participation in the activities, they consistently demonstrate negative affect during data collections, or they are not able to comply with the requested assessment and intervention schedules.

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).

Discomfort while changing clothing.

Electrical risks.

Aim 1: Risk of falling with poor arm protective reactions when wearing the garment that challenges arm movement.

Aim 1: Risk of being frustrated by garment that challenges arm movement

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. Participants are asked to engage in typical daily activities. Assessment equipment is non-invasive. The garment materials used have been safely used in a variety of DIY and commercial projects. The level of battery power used matches that safely used in a variety of common wearable devices like watches, Fitbits, and hearing aids.

*(*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?

Discomfort while changing clothing – We will ensure a private place and presence of a familiar caregiver, such as a family member or teacher, for assistance if desired.

Risk of a short circuit. This can occur if different parts of the electrical circuit come into contact. We will minimize the risk of contact among electrical components by keeping electrical components away from one another in the garment and insulating electrical components, as well as protecting them from short circuiting when wet by waterproofing the electronics for garments to be kept in the home. We will also insulate electrical components to prevent them from contacting the body. A standard of less than 30V is recommended for electrical components for wearable electronics and

our electronics will be well below that level. Risk with the sensor garments are minimal due to a) very low voltages and currents output from the microcontroller, typically 3.3V-5V and between 10-20mA; b) small batteries, with less than 1000 mAh of charge capacity and a voltage typically 3.7V and not higher than 9V; and c) we will include a fuse with the battery supply circuit or will use a microcontroller with short circuit detection. With these voltage and current levels, one would not feel anything when contacting the conductive thread with part of their body even if they are perspiring. Should something go wrong with the circuit (for example, a short), we will use fuses to prevent energy leakage and heat generation from batteries. If the fuses fail to disconnect the battery from the circuit should the current go above the desired threshold, one might feel tingling when contacting the conductive thread and may feel warming of the battery. Participants will be informed each session to communicate if they feel any tingling and/or heat from the battery. In this case, the garment will be doffed and the problem fixed. Experimenters and parents will also be advised to check the participant's skin for any signs of redness or discomfort after each wearing session. Finally, all garments will be designed to be quickly doffed. Participants will be advised not to wear the garments in the rain. Participants will also be advised to allow the garments to air dry should they get wet.

With regard to washing, we will provide participants and research team members instructions on how to hand wash the garments (attached). This will include instructions for removing the battery unit before washing and allowing the garment to thoroughly dry before reattaching the battery unit. The sensors are made of metals that do not react with water so they can get wet and can be washed. The University of Minnesota research team has conducted washability tests using the sensors and circuit assembly techniques that are used in the garments for this study. No effects of washing were observed.

Aim 1: Risk of falling with poor arm protective reactions when wearing the garment that restricts arm movement. [Note this garment is only used for Aim 1 so this risk does not apply to the other aims.] We will minimize this risk be ensuring an experimenter is closely supervising participants and avoiding high-risk fall tasks like walking on stairs and over obstacles. In addition, while the elastic makes movement a little more challenging, it does not prevent movement of the arm.

Aim 1: Risk of being frustrated by garment that challenges arm movement. We will minimize this risk by talking to participants to clarify their level of comfort with this task. Typical 3-30 year olds should be able to understand why we are asking them to do this, that it will only last a brief time, and that we will be close by to ensure they are safe. Participants may opt out of this testing if engagement in this testing causes them anxiety.

Describe any potential direct benefits to participants.
Aim 1: Test how effectively a garment with thread sensors stitched to look and feel like typical seams measures movement and activity for people 3-30 years old with typical movement
None.

Aim 2: Test whether daily use of a low-tech soft inflatable arm support garment impacts arm function across time for children 3-14 years old with arm movement impairments, using the sensors from the first aim to track movement and activity across time.
Participants may find that the support garment helps improve their arm function when worn.
Participants may gain improved arm function across time from using the support garment daily for activity.

Describe any potential future benefits to this class of participants, others, or society.
Aim 1: Test how effectively a garment with thread sensors stitched to look and feel like typical seams measures movement and activity for people 3-30 years old with typical movement
Sensors integrated within garments may provide a mechanism for activity assessment and environmental control in the natural environment that does not stigmatize users by being bulky and

unattractive. These sensors also have other potential applications, such as warning athletes or people after surgery when they are moving into undesirable ranges.

Aim 2: Test whether daily use of a low-tech soft inflatable arm support garment impacts arm function across time for children 3-14 years old with arm movement impairments, using the sensors from the first aim to track movement and activity across time.
User-controlled pneumatic support garments may serve as more functional, affordable, comfortable, aesthetically pleasing movement assisting garments for people with disabilities than the traditional hard, bulky, metallic robotic and exoskeletal devices currently available.

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

9. **COMPENSATION**
Will participants be compensated for participation?
If so, please include details.

Aim 1: Test how effectively a garment with thread sensors stitched to look and feel like typical seams measures movement and activity for people 3-30 years old with typical movement
Yes, via a $15 gift card at the last visit. If participants are unable to complete the entire study, they will receive a gift card worth $5 for each of the 3 potential movement data assessments they completed.

Aim 2: Test whether daily use of a low-tech soft inflatable arm support garment impacts arm function across time for children 3-14 years old with arm movement impairments, using the sensors from the first aim to track movement and activity across time.
Yes, via a $40 gift card at the last visit. If the participant is unable to complete the entire study but completed the entire baseline phase, they will receive a gift card worth $15.

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)

Yes. Each participant will have a unique numerical ID that will be used to name all of the participant's electronic files. A password protected file linking participant IDs and personal information will be stored on a password protected computer in a lockable lab at the study site where the participants were recruited. Personal information about participants will not be shared by researchers across sites. Information will be shared using IDs. No documents including informed consents will contain both IDs and personal identifying information about participants.

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)

Paper records will be stored in a lockable cabinet in a lockable lab at the study site where the participant was recruited and data were collected (UD, VT, UM). Access to these files will be restricted to key personnel and will be supervised by each site's PI.

Digital records will be stored on password protected university servers or on external hard drives or password protected computers in a lockable lab at each site. Digital records will be shared across

sites using Box Secure Storage. UM has a license for this secure data storage and sharing platform. The security features of that license include encryption, activity logging, Duo Two-Factor Authentication, and access controls such as view-only access, and the implementation is specifically designed to be compliant with security standards for private-highly restricted data. Box allows for uploading and storage of large data files (up to 15 GB per file) like the video files in this project, encryption for data in transit and at rest, and multiple data centers with reliable power centers and backup systems. Only invited users will be able to access the secure Box account created for this project. Only PI's and senior research team members will be invited to join this account. Access will be terminated for anyone no longer working on the project.

How long will data be stored?

Data will be kept for a minimum of three years after completion of the project.

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

Data files linking participant identifying information with data will be erased after three years of completion of the project.

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?

<u>Aim 1: Test how effectively a garment with thread sensors stitched to look and feel like typical seams measures movement and activity for people 3-30 years old with typical movement</u>
These results will be statistically analyzed as a group to determine reliability within a session and across sessions as well as validity of movement measurement with the garment and of the activity algorithms.

<u>Aim 2: Test whether daily use of a low-tech soft inflatable arm support garment impacts arm function across time for children 3-14 years old with arm movement impairments, using the sensors from the first aim to track movement and activity across time.</u>
These results will be analyzed both using group statistical methods (e.g. differences with and without the support garment) as well as via single-case analysis methods (e.g. changes in performance during intervention relative to baseline within each of the multiple participants). Results will generally be reported for the group or subgroups but may be reported for individuals without the provision of any personal information that could identify those individuals.

11. **CONFIDENTIALITY**
Will participants be audiotaped, photographed or videotaped during this study?

Yes, photographed and videotaped.

How will subject identity be protected?

Subject information will be stored in a lockable cabinet in a lockable room at the site of data collection or on password protected computers and external hard drives. In reporting the results, no names or personal information will be used and the data will be mainly reported in aggregate form. The only information used to identify videos and other digital data will be the IDs and dates. Videos and photographs will be used for presentations. Participants will be given the opportunity to consent

for this purpose.

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)

__X__ 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. After approval by UD's IRB, the requested IRB of record, PI Dunne and Co-PI Hoshuh will submit the project to the IRB at UM and Co-PIs Jones and Martin will submit the project to the IRB at VT for approval.

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

Forthcoming.

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

Consents & Assents
Aim_1_Consent
Aim_1_Assent
Aim_2_Consent
Aim_2_Assent

Advertisements
Aim_1_Flyer (pdf)
Aim_2_Flyer (pdf)

Questionnaires
Aim_1_Aim_2_Baseline_Perception_Survey
Aim_2_Intervention_Perception_Survey
Caregiver Priorities & Child Health Index of Life with Disabilities (CPCHILD)_Questionnaire
Health & Demographic Form
Log_Baseline_Phase
Log_Intervention_Phase
Log_Post_Intervention_Phase

Assessments
BOT_2
GMFCS
MACS_Complete
CFCS
Measurement_Guide

Other
Garment Washing Instructions
Script for 3-6 year old participants Aim 1
Script for 3-6 year old participants Aim 2