SmarToyGym: Smart Detection of Atypical Toy-Oriented Actions in At-Risk Infants (Protocol)

NCT #02813889

MAY 19, 2021

Protocol Details

Basic Info

Confirmation Number:	**cigajiii**
Protocol Number:	**822487**
Created By:	**VIVIO, NICHOLAS**
Principal Investigator:	**JOHNSON, MICHELLE J**
Protocol Title:	**SmarToyGym: Smart detection of atypical toy-oriented actions in at-risk infants**
Short Title:	**SmarToyGym**
Protocol Description:	**This project develops a SmarToyGym where sensorized, wireless toys are placed within the reach of infants to elicit body, arm/hand and leg movements. The objective is to conduct pilot testing of the SmartToyGm with atypical and typical infants. A battery of metrics will be identified to discriminate between high and low risk infants, thus allowing for earlier neurodevelopmental intervention.**
Submission Type:	**Biomedical Research**
Application Type:	**EXEMPT Category 2**

Resubmission*
Yes

Hospital Sites
Will any research activities and/or services be conducted at a Penn Medicine affiliated hospital site?
No

Study Personnel

Principal Investigator

Name:	**JOHNSON, MICHELLE J**
Dept / School / Div:	**4482 - RM-Rehabilitation Medicine**
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Email:	**johnmic@pennmedicine.upenn.edu**
HS Training Completed:	**Yes**
Training Expiration Date:	**09/07/2015**
Name of course completed :	**CITI Protection of Human Subjects Research Training - ORA**

Study Contacts

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Dept / School / Div:	**4482 - RM-Rehabilitation Medicine**
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HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Other Investigator

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HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed :	

Responsible Org (Department/School/Division):

4482 - RM-Rehabilitation Medicine

Key Study Personnel

Name:	**OYERINDE, ESTHER**
Department/School/Division:	**DM-Department of Medicine**
HS Training Completed:	**Yes**
Training Expiration Date:	**03/13/2021**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**HO, ELAINE S**
Department/School/Division:	**PH-Pharmacology**
HS Training Completed:	**Yes**
Training Expiration Date:	**10/17/2020**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**SALUJA, RACHIT**
Department/School/Division:	**School of Engineering**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**GAARDSMOE, SAMUEL**
Department/School/Division:	**Health System**
HS Training Completed:	**Yes**
Training Expiration Date:	**05/31/2018**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**TORRES, WILSON**
Department/School/Division:	**Health System**
HS Training Completed:	**Yes**
Training Expiration Date:	**04/17/2019**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**PATEL, ANIKET C**
Department/School/Division:	**School of Engineering**
HS Training Completed:	**Yes**
Training Expiration Date:	**01/27/2021**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**BOGEN, DANIEL K**
Department/School/Division:	**Research Services**
HS Training Completed:	**Yes**
Training Expiration Date:	**04/07/2017**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**FREGENE, NICOLE**
Department/School/Division:	**Health System**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**SANDERS, OZELL P**
Department/School/Division:	**Regulatory Affairs**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**LYSENKO, SOFIYA**
Department/School/Division:	**Health System**
HS Training Completed:	**Yes**
Training Expiration Date:	**06/19/2020**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**LOEB, HELEN**
Department/School/Division:	**Regulatory Affairs**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**GIBBS, KATHLEEN A**
Department/School/Division:	**PE-Pediatrics**
HS Training Completed:	**Yes**
Training Expiration Date:	**09/27/2020**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**SEETHAPATHI, NIDHI**
Department/School/Division:	**Bioengineering**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**KORDING, KONRAD P**
Department/School/Division:	**Bioengineering**
HS Training Completed:	**Yes**
Training Expiration Date:	**07/13/2020**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**SOBREPERA, MICHAEL**
Department/School/Division:	**Health System**
HS Training Completed:	**Yes**
Training Expiration Date:	**09/02/2019**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**ZHAO, SUSAN**
Department/School/Division:	**Health System**
HS Training Completed:	**Yes**
Training Expiration Date:	**09/17/2019**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**MORRIS, HEIDI**
Department/School/Division:	**Health System**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**CHAMBERS, CLAIRE**
Department/School/Division:	**Bioengineering**
HS Training Completed:	**Yes**
Training Expiration Date:	**10/24/2020**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**SHOFER, FRANCES S**
Department/School/Division:	**EG-Emergency Medicine**
HS Training Completed:	**No**
Training Expiration Date:	
Name of course completed:	

Name:	**CHEN, YUDAN**
Department/School/Division:	**School of Engineering**
HS Training Completed:	**Yes**
Training Expiration Date:	**05/13/2021**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Name:	**KONG, GAIQING**
Department/School/Division:	**Bioengineering**
HS Training Completed:	**Yes**
Training Expiration Date:	**10/29/2020**
Name of course completed:	**CITI Protection of Human Subjects Research Training - ORA**

Disclosure of Significant Financial Interests*
Does any person who is responsible for the design, conduct, or reporting of this research protocol have a **FINANCIAL INTEREST**?
No

Penn Intellectual Property*
To the best of the Principal Investigator's knowledge, does this protocol involve the testing, development or evaluation of a drug, device, product, or other type of intellectual property (IP) that is owned by or assigned to the University of Pennsylvania?
Yes

If yes, please provide any readily available information on such IP. For example, a brief description of the IP, any relevant docket number (if disclosed to the Penn Center for Innovation (PCI), patent application or patent numbers, inventor's names, and/or other relevant details.*
Michelle Johnson is one of the inventors.

Certification
I have reviewed the *Financial Disclosure and Presumptively Prohibited Conflicts for Faculty Participating in Clinical Trials* and the *Financial Disclosure Policy for Research and Sponsored Projects* with all persons who are responsible for the design, conduct, or reporting of this research; and all required Disclosures have been attached to this application.
Yes

Biomedical Research

Human Source Material*
Does this research include collection or use of human source material (i.e., human blood, blood products, tissues or body fluids)?
No

Medical Information Disclosure*
Does the research proposal involve the use and disclosure of research subject's medical information for research purposes?
Yes

If the answer is YES, indicate which items is is provided with this submission:

Modified research informed consent document that incorporates HIPAA requirements

CTRC Resources*
Does the research involve CTRC resources?
No

Pathology and Laboratory Medicine Resources*
Will samples be collected by hospital phlebotomy and/or processed or analyzed by any of the clinical laboratories of the University of Pennsylvania Health System?
No

Research Involves Apheresis, Cell Collection, and/or Blood Product Collection*
Does this research involve collection of blood products in the Penn Donor Center and/or the use of apheresis for treatment or collection of cells or other blood components?
No

Research involving blood transfusion or drug infusions*
Will your research involve blood transfusion or infusion of study drug in 3 Ravdin Apheresis Unit for research purposes?
No

Trial in Radiation Oncology
Is this research a prospective trial being done in Radiation Oncology, and if so, has this protocol been approved by the Radiation Oncology Protocol committee?
No

Study in Radiation Oncology
Is this research a retrospective study being done in Radiation Oncology, and if so, has this project been reviewed by the Radiation Oncology Clinical Research Group?
No

Use of UPHS services*
Does your study require the use of University of Pennsylvania Health System (UPHS) services, tests or procedures*, whether considered routine care or strictly for research purposes?
No

Primary Focus*
Other

Protocol Interventions

	Sociobehavioral (i.e. cognitive or behavioral therapy)
	Drug
	Device - therapeutic
x	**Device - diagnostic (assessing a device for sensitivity or specificity in disease diagnosis)**
	Surgical
x	**Diagnostic test/procedure (research-related diagnostic test or procedure)**
	Obtaining human tissue for basic research or biospecimen bank
	Survey instrument
	None of the above

The following documents are currently attached to this item:

There are no documents attached for this item.

Department budget code

None

Protocol

Objectives

Overall objectives
We aim to develop a Gym where sensitized, wireless toys are strategically hung and placed within reach of infants to elicit toy-oriented body and arm/hand movements. Each toy will be equipped with sensors capable of measuring the infant's grasping actions such as squeezing, pinching, tilting, etc. A low-cost 3D motion capture system will be used to collect video data and the infants' reaching and body kinematics in response to the toys. A pressure mat will be used to measure postural changes to detect weight shifts, rolling, crawling and other movements away from the initial posture. By capitalizing on these wireless and low-cost technologies, it will permit the regular and non-invasive monitoring of infants, which can lead to detailed, non-obtrusive, quantitative evaluation of motor development. In this vein, we also aim to conduct proof-of-concept testing of the Gym with atypical and typical developing infants. We will include infants' ages 3 to 11 months who are categorized as high-risk or low-risk using the Bayley Infant Neurodevelopmental Screener.

Background
An estimated 5 to 10 percent of children have developmental disabilities (Rydz 2005), and an increase in survival rates of medically fragile infants has led to an increased number of children with functional impairments later in life (Vohr et al 2003). Particularly, pre-term and low birth weight infants as well as those exposed to brain injuries due to a central nervous injury insults such as asphyxia, neonatal seizures, prenatal drug use, or maternal infections are at increased risk for developmental delays and neurologic impairment. Successful early detection of delay or impairment in at-risk infants depends on the effectiveness of standard clinical scales, many of which are not sufficiently sensitive to screen infants younger than 6 months (Leonard et al 2001). For example, one popular scale was reported to have a positive predictive value of 67 percent for motor or cognitive impairment, i.e., high risk infants identified at 6 months using the screening tool were 67 percent likely to have a cognitive impairment at

12 months. The same scale is even less predictive for infants deemed moderate risk. While an infant ages, these scales do become more accurate and can better predict which infants will develop disabilities at 2 and 3 years old (Aylward and Verhust 2000). However, currently there is no tool that is definitively predictive of functional impairment for infants less than one year. The earlier detection of motor delays or impairments provides the opportunity for earlier treatment, thus leading to better health outcomes over the lifespan (McIntyre et al 2011). Recognizing this, primary care pediatric physicians now recommend that infants at risk for delayed achievement of developmental milestones have a developmental evaluation at least two times during their first year of life (Spittle et al 2008). Unfortunately, while the physicians' recommendation is well intended, the current screening tools provide them with much less than perfect information. Note: For complete bibliography see grant attached to this submission. References directly related to the above background information can be found below. Aylward G, Verhulst S. Predictive utility of the bayley infant neurodevelopmental screener (BINS) risk status classifications: Clinical interpretation and application. Dev Medicine & Child Neurology 2000; 42:25 31. Leonard C, Piecuch R, Cooper B. Use of the bayley infant neurodevelopmental screener with low birth weight infants. Journal of Pediatric Psychology. 2001; 26 (1):33 40. McIntyre S, Morgan C, Walker K, Novak I. Cerebral palsy--don't delay. Dev Disabil Res Rev. 2011 Nov; 17(2):114-29. PMID:23362031 Rydz D, Shevell MI, Majnemer A, Oskoui M. Developmental Screening, Journal of Child Neurology. 2005; 20(1): 4-21 Spittle A, Doyle L, Boyd R. A Systematic review of the clinimetric properties of neuromotor assessments for preterm infants during the first year of life. Developmental Medicine & Child Neurology. 2008;50:254 266. Vohr B, OShea M, Wright LL, Longitudinal multicenter follow-up of high-risk Infants: why, who, when, and what to Assess, Seminars in Perinatology. Aug 2003; 27(4): 333 342.

Study Design

Design

The proposed research is specifically designed to investigate the ability of a novel tool to identify atypically developing infants from their typically developing peers. There will be an initial portion for usability feedback of hardware and software. For testing: For the first portion of the study (Part A) we will recruit up to 10 infants for analysis for up to two sessions each. After this initial testing, twenty-four infants will be recruited to participate, including 12 who are developing typically and 12 who are identified as at-risk for neuromotor delay. Infants with typical development will be at least 3 months and less than 11 months of age, score in the low-risk category on the Bayley Infant Neurodevelopmental Screener (BINS), score a greater than 85 on all sub-scales of the Bayley Scale of Infant Development (BSID-II), have no history of significant cardiac, orthopedic, or neurological condition, and gestational age at least 37 weeks. Infants at risk for neuromotor delay will be at least 3 months and less than 11 months of age (corrected for preterm birth if applicable), score in the moderate or high risk categories on the BINS, and score an 85 or less on the motor sub-scales of the Bayley Scale of Infant Development (BSID-II). In an effort to decrease variability of the data, infants in each group will be further stratified into an older group (8-10+ months) and a younger group (3-5 months).

Study duration

1) We estimate that it will take two years from the date of IRB approval to enroll all subjects and complete the study. 2) At minimum, some subjects may be asked to experienced the Gym 1x. At most, a subject will be asked to use the Gym for up to 5 consecutive days. Each day the infant will use the gym, both with and without toys, for 3 minutes. 3) 5/01/2015 - 8/01/2017

Characteristics of the Study Population

Target population

Two populations will be involved: 1. Infants exhibiting typical development between 3 months and 11 months of age 2 . Infants exhibiting atypical development (at-risk for neuromotor delay) between 3 months and 11 months of age.

Subjects enrolled by Penn Researchers

50

Subjects enrolled by Collaborating Researchers
0

Vulnerable Populations

x	**Children Form**
	Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form
	Fetuses and/or Neonates Form
	Prisoners Form
	Other
	None of the above populations are included in the research study

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject recruitment
Infants with typical development will be recruited from siblings of patients at The Childrens Hospital of Philadelphia (CHOP), and through local parent groups. Potential candidates in the at-risk group will be invited to participate through a variety of mechanisms within CHOP. The primary avenue for recruitment will be through the Neonatal Follow-up clinic at CHOP. Infants who are receiving services at the Center for Rehabilitation will also be invited to participate. In efforts to recruit a population that is easily testable on multiple days, testing may be done at a local daycare.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?
No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*
Will subjects be financially compensated for their participation?
Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

For the usability portion the individual caregivers will be compensated 10 dollars. Part A Families will be compensated 50 dollars for the testing. Families participating in Part B will be compensated 100 dollars for their first visit (clinical evaluation plus first gym session) and 25 dollars for each session thereafter ($200 total). Should the authorized representative of the research participant (infant) decide to withdrawal prior to completion of the study, compensation will be prorated. Compensation will be through a reloadable ClinCard. Any daycare that agrees to participate in the study will also receive a 100 dollar gift card for infant/children's toys and activities.

Study Procedures

Suicidal Ideation and Behavior
Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?
No

Procedures
Prior to being assessed by the therapist, the parent or legal guardian will be consented. They will also be asked to fill out general surveys including, a demographic survey, and a case report form, and a user feedback survey which provides relevant information, on both the family's and infant's medical history and experience. After being assessed by a certified therapist for approximately one hour, both atypical and typical infants will be observed playing within the Gym. The environment will be prepared such that only items safe for infants will be in the testing and play areas. Fort the usability: The caregiver may be asked to closely observe and examine the hardware and the software of the system. The caregiver may then offer the toy to the infant for familiarization, observe the infant play and capture and upload a video of this interaction. The caregiver may be asked to complete a feedback and observation survey that will provide relevant information about the interaction and software and hardware experience. Part A) Data quantifying infants actions with and without toys will be collected in one or two sessions. Infants will be tested for their reaction to the gym without toys and then their reactions with 1 or multiple toys. The baby will be placed in the center of the gym. The baby will be allowed to settle and play for 1 minute then data will be collected again for 1-3 minutes. Each session will be recorded using the Microsoft Kinect camera. Arm/hand/leg position data will be collected with the kinect camera, grasp pressure and forces will be collected, toy position and angular data will be collected via Kinect and inertial sensors, and central pressure data will be collected via the novel mat. Video data mapping their reaction may be collected using "Autism and Beyond" developed for research by Duke University. Part B) Data quantifying infant actions will be collected for 5 consecutive days under two conditions: with toys and without toys (control); the no toys condition will be tested first and the toy condition immediately after. The data from the no toy condition will be used to adjust the observations in the toy condition and will be used to account for the infants baseline actions per day. A test session will proceed as follows: First, the infant will be placed on his or her back at a pre-determined position on the gym mat in the no toy condition. Data will be collected for 3 minutes. The infant will be removed. The toys will be placed in the gym and adjusted for the infant reach; hanging toys will be placed at about 75% of the infants reach. After, the infant will be placed again with respect to the pre-determined position. To detect an infants intentional movement toward a specific toy, the location of each toy will be randomized within possible locations per toy type. The baby will be allowed to settle and play for 1 minute then data will be collected again for 1-3 minutes. Each session will be recorded using the Microsoft Kinect camera. Arm/hand/leg position data will be collected with the kinect camera, grasp pressure and forces will be collected, toy position and angular data will be collected via Kinect and inertial sensors, and central pressure data will be collected via a pressure mat. General Procedure: A caregiver or parent will be seated at the head of the baby (out of babys sight) to provide comfort if needed. Infants will be required to be alert and unhampered by clothing with their limbs free to move. They will be placed on their backs and allowed to roll or crawl as long as they stay within the perimeter of the device. If infants become frustrated (cries and is unsettled), the parent will be asked to pick them up and calm them. The trial will be restarted. If several attempts are unsuccessful, the session will be ended and attempted later in the day. We will take precautions to minimize the likelihood of participants experiencing any injury or discomfort. To avoid bumps, bruises or crashing into toys, participants will be supervised at all times by a trained study team member during CHOP sessions, including by a licensed pediatric physical therapist during developmental evaluations, and caregivers will be trained to place infants on their backs during home Gym play sessions. Caregivers will also be able to reposition their infants if he or she is uncomfortable.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception
Does your project use deception?
No

International Research
Are you conducting research outside of the United States?
No

Analysis Plan
We will identify a battery of metrics derived from kinematic and kinetic measurements of infant movement that are able to discriminate between atypical and typical infants and evaluate neuromotor impairments. Metrics quantifying one and two-handed reach and grasp actions as well as leg and body actions will be derived from the data. We will also determine the reliability/reproducibility of our methods across the repeated measurements taken in the home. We also will examine how each metric correlates with the BINS and BSITDIII scores. The key primary metrics are unimanual and bimanual arm use, leg use, grasp forces, arm position when being used, and arm velocity when used. Secondary measures will be center of pressure from starting position, toy speed, toy acceleration, toy tilt angle, arm synchronicity, leg synchronicity, leg distance to toy, and respective differences in the percentage of arm use for reaching and for grasping. Given our long-term goal of detecting the emergence or lack of emergence of multiple milestones in the development of infants, we will examine a variety of metrics. Some of these milestones are the emergence of hand dominance using the relationship between the right and left hands; the emergence of unimanual or bimanual reaching using the relationship of the hand position to the toy, the hand speed, the frequency of movements; the emergence of unimanual grasping using grasping forces, the emergence of undifferentiated bimanual grasping detected by monitoring when the right and left arms start to move together toward a toy, and the emergence of differentiated bimanual grasping. For each variable, we anticipate having 120 data points per second for a minimum of 180 seconds. Initially, kinetic metrics, and frequency of reaching and grasping will be summarized using means and standard deviations each day, to assess for variability. Intraclass correlations coefficients (ICC) will be calculated to examine reliability/reproducibility of each measurement over the 5 days. If the ICCs are relatively high (.9), we will average the 5 days to create a single summary figure for each measurement to test. Using these summary figures, we will first perform 2-sample t-tests or Wilcoxon rank sum tests on the averages or ranks of each metric respectively, where the two groups represent atypical and typical infants, stratified by age group. Given our stratified groups of younger/older and typical/atypical infants, we anticipate having relatively large differences across most measures. Should the ICCs be low, due to learning we will use a 2-factor ANOVA in repeated measures where day would be the repeated measure and age group and infant type would be the 2 factors. For non-normal distributions, such as many zeroes for the atypical group or other non-normal/skewed distribution, we will use either Poisson (log-linear) regression or a Negative Binomial (ZINB) regression. All analyses will be performed using SAS statistical software. As we are looking for proof of concept, we will be looking for relatively large differences between atypical and typical babies. In order to build a machine algorithm to analyze the baby data, we will build a test data set from publically held you tube videos. We will pull YouTube videos from babies between the ages of 1month and 12 months.

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject Confidentiality
All study personnel will have access to a locked file cabinet containing consent forms, evaluation assessments, and collected data. The locked file cabinet will be located at the Rehabilitation Robotics Lab, Philadelphia, PA, 19146. Both electronic data and hard copy records will be kept for a minimum of 10 years. Electronic data will be kept on password protected computers. After 10 years, any documents no longer needed will be destroyed by secure shredding at Penn Rittenhouse and electronic data will be deleted from computers. Research subjects will be identified in the research data by code and at no time will a direct link exist between collected data and research subjects. When data results are reported they will be presented in aggregate form (i.e. group characteristics only) and no individual identifiers will be used. Dr. Kording's lab will be helping to develop the algorithm. Data will be shared with them and it may be necessary to have data stored on their password protected computers at Hayden Hall (106 Hayden Hall, 240 S 33rd St, Philadelphia, PA 19104) CHOP and Penn maintain strict policies, systematic procedures and sufficient resources for data management in compliance with HIPAA and IRB regulations for safeguarding participant information to protect against loss of confidentiality. Electronic data will be stored in secure, HIPAA-compliant, password-protected systems. Hard copies of data collection instruments and training logs will be stored in a locked cabinet in a

locked office or laboratory. Participants will be assigned a unique identifier that contains no protected health information. Access to the identifiers of the coded data will be controlled by the PI and Co-PI. All members of the study team will undergo Human Subjects Research training. Human subjects safety monitoring will be the responsibility of the Co-PI. All adverse events will be reported in accordance with IRB and NIH requirements.

Sensitive Research Information*
Does this research involve collection of sensitive information about the subjects that should be excluded from the electronic medical record?
No

Data Disclosure
Will the data be disclosed to anyone who is not listed under Personnel?
Yes, Sam Pierce, a researcher at CHOP is not listed under Personnel. Also, Elliot Warshowsky, research assistant to Dr. Helen Loeb, will have access to the data. HIPAA and CITI are attached to the protocol.

*Data Protection**

- x **Name**
- x **Street address, city, county, precinct, zip code, and equivalent geocodes**
- x **All elements of dates (except year) for dates directly related to an individual and all ages over 89**
- x **Telephone and fax number**
- x **Electronic mail addresses**
- **Social security numbers**
- x **Medical record numbers**
- **Health plan ID numbers**
- **Account numbers**
- **Certificate/license numbers**
- **Vehicle identifiers and serial numbers, including license plate numbers**
- **Device identifiers/serial numbers**
- **Web addresses (URLs)**
- **Internet IP addresses**
- **Biometric identifiers, incl. finger and voice prints**
- x **Full face photographic images and any comparable images**
- **Any other unique identifying number, characteristic, or code**
- **None**

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?
No

Consent

1. Consent Process

Overview
Informed consent will be obtained by the research physical therapist, the trained study coordinator, or an investigator, and will be documented in the electronic database. The family will have the opportunity

to ask questions throughout the entire process. The parent or legal representative must provide written informed consent prior to the start of any study activities. Written assents of minors will not be obtained due to the age of the participants. Regarding the location of where informed consent will be obtained, and due to the fact that the SmarToyGym and tests are portable, testing can occur at CHOP, PIRM, participants' homes, and local day care centers. Informed consent could therefore be obtained in any of these locations.

Risk / Benefit

Potential Study Risks
The risks are minimal and all testing will be non-invasive. All treatment and assessment activities in the proposed research present no more than minimal risk to study participants. Risks include those involved with any developmental assessment or home play time, including bumps and bruises from poor control of movement or crashing into toys. Infants may also become frustrated if they attempt motor activities that they are as yet unable to perform, such as reaching or manipulating a toy. The environment will be prepared such that only items safe for infants will be in the testing area. Participants at risk for motor delays may rely on life-sustaining medical equipment, such as external respiratory support. For these babies, routine daily risk includes breaches in the medical support equipment (such as decannulation), which can happen during therapy sessions, floor play time, clothing changes, and generally anytime throughout the day. If any study participant requires life-sustaining medical equipment, s/he will be accompanied at all times by a caregiver trained to respond to any breaches in medical support. Enrollment of these babies will also be conducted in consultation with the medical team. Additionally, protected health information will be collected as part of study records, and breaches of this information outside of the study team resulting in loss of confidentially is an unlikely but potential risk. Alternatives to participation in this study include not participating or seeking a developmental evaluation elsewhere. All risks and alternatives will be explicitly stated in consent documents.

Potential Study Benefits
There are no direct benefits to participants in this study. The knowledge gained will inform early detection and rehabilitation practices for other children at risk for neuromotor impairment, may lead to the development of treatment interventions, and the risk to participants is minimal.

Risk / Benefit Assessment
Minimal risk

General Attachments

The following documents are currently attached to this item:

There are no documents attached for this item.