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

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University of Pennsylvania

Penn Medicine Rittenhouse
Department of Physical Medicine & Rehabilitation

Informed Consent and HIPAA Authorization Form

Name of Study Volunteer: _____

Protocol Title: SmarToyGym: Smart detection of atypical toy-oriented actions in at-risk infants

Principal Investigators:
Michelle J. Johnson, PhD
Laura Prosser, PT, PhD
Daniel Bogen, MD, PhD
Philip Bryant, DO

Contact Person:
Michelle J. Johnson PhD
1800 Lombard Street, Philadelphia, PA, 19146
Office: (215) 893 – 2665
Lab: (215) 893 – 2695

Why am I being asked to volunteer?

Your child is being invited to participate in a research study. Your child's participation is voluntary which means you can choose whether or not you want them participate. If you choose for them not to participate, there will be no loss of benefits to which you are otherwise entitled. *Your child has been invited to participate in this study because your child exhibits either typical or atypical neuromotor motor development and is between the age of 3 and 11 months.*

Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of your child being in this study, and what they will have to do in this study. The research team is going to talk to you about the research study, and they will provide you with this consent form to read. You may also decide to discuss it with your family, friends, or primary care provider. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of this study is to develop a Gym, which could consist of sensitized, wireless toys,strategically hung or placed within reach of infants to elicit toy-oriented body and arm/hand movements. Toys will be equipped with sensors capable of measuring the infant's grasping actions such as squeezing, pinching, tilting, etc. By developing a better more accurate metrics and a better screening device than what is currently available to clinicians, our ultimate goal is to facilitate earlier interventions for infants with neuromotor impairments.

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How long will I be in the study?

Your child's participation in this the study will last from 15 minutes to a maximum of 2 hours, for up to 5 consecutive days.

How many other people will be in this study?

Your child will be one of approximately 44 participants in this research study.

What am I being asked to do?

Your participation in this study may include the following steps:
Prior to being assessed by the therapist, as the parent or legal guardian will be provided with, and asked to sign, an informed consent. You will also be asked to fill out a demographic survey and case report form, which provides relevant information on your family's and child's relevant medical history.

Usability

1) **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.**

Testing

1) Your child may be assessed by a certified therapist that is part of the research team in order to determine if he/she is at risk of atypical neuromotor development or will be considered a control. This assessment may last approximately one hour.
2) (PART A) Your child may be asked to interact with the Gym for up to 1 hour. Your child may interact with the Gym both with and without the toys (toys may be presented alone or together) for 1-3 minutes at a time. Each session should last no more than 30 minutes including set-up. One or two sessions will occur.

3) (PART B) Your child may be asked to interact with the Gym for up to 5 consecutive days. Your child may interact with the Gym both with and without the toys for 3 minutes at a time. Each session should last no more than 30 minutes.

What are the possible risks or discomforts?

The risks associated with participation in either part of this study include:

- Pain or muscle bruising in the event your child bumps into the Gym.
- If your child relies on life-sustaining medical equipment, such as external respiratory support, there is the risk of a breach in the medical support during the study, similar to any risk during therapy sessions or floor play time. A trained caregiver will be required to accompany your child at all times during the study.
- While every precaution will be taken to secure any personal information and protect privacy, a breach of confidentiality is possible.

There may be some unknown or unanticipated discomforts or risks in addition to those specified above. Every precaution will be taken to assure your child's personal safety and to minimize discomfort. If your child is experiencing discomfort you should inform a member of the research team immediately.

Any new findings discovered during the course of this project which may affect your willingness to continue participation will be provided to you.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

Your child is not expected to receive any major benefits from being in this research study. However, the information obtained from this study may be useful scientifically and may prove helpful to other members of society who find themselves in similar situations in the future.

What other choices do I have if my child does not participate?

You may choose not to participate in the research study.

Will I be paid for being in this study?

For the Usability Part: You will receive $10 to complete the feedback.

For Part A: You will receive $50 dollars to complete this portion of the study.

For Part B: You will receive $100 dollars after the first visit, at which a clinical evaluation and the first assessment in the toy gym will take place. An additional $25 dollars will be paid for the four remaining sessions, up to a total of $200 dollars.

Will I have to pay for anything?

As a participant in this study, you or your insurance company will not be responsible for the costs of any study related activities such procedures required for the study. Insurance companies or other third party companies will not be billed for research purposes.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania or The Children's Hospital of Philadelphia (CHOP) to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. Your participation in this study may also be stopped at any time by the Principal Investigator without your consent because:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study's Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

What information about me may be collected, used or shared with others?

Information in the medical record, results of physical examinations, medical history, lab tests, or protected health information such as name, address, date of birth, audio, video or photographic images, and telephone and email, may be collected as part of this research study.

The research team will use and share your private medical information only for this study; however, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right.

Who can use and share my information? How will my personal information be protected?

The study investigators will store your private medical information in a safe place. Only people with permission will be able to see or use it. This is required by federal and state privacy laws, such as the Health Insurance Portability and Accountability Act (HIPAA). These laws protect your private medical information if they also have details that could reveal your identity such as birthdates, initials, addresses, and social security numbers can identify you. The law also protects information that may also identify your family, your housemates, or your employer.

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we create, collect, or use as part of the research. This permission is called an authorization. By signing this form, you authorize the use and sharing of the following information for this research:

1. Your medical records and information we collect from you about your medical history and your experience at The Children's Hospital of Philadelphia (CHOP) and The University of Pennsylvania Hospital System (UPHS).
2. Clinical and research data collected and observations made during your participation in the research.

By signing this form, you authorize the following persons and organizations to receive your protected health information for purposes related to this research: members of the research team from The Children's Hospital of Philadelphia, The University of Pennsylvania Hospital System (UPENN), and The University of Pennsylvania. In addition, the federal government sponsor of this project, the National Science Foundation, Good Shepherd Penn Partners, and both CHOP and UPENN's Institutional Review Board, which are responsible for ensuring your welfare and rights as a research participant, may review and or photocopy study records which may, if they feel it necessary, identify you as a participant.

If information obtained in this study is published, it will not be identifiable as your results unless you give specific permission. Good Shepherd Penn Partners and partnering entity will comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices provides more information on how we protect your information. A copy of the notice will be provided to you.

Who, outside of CHOP and UPHS, might receive my information?

Members of research team who are employed by other departments at the University of Pennsylvania. These include the school of engineering and the school of medicine. In addition, the federal government sponsor of this project, the National Science Foundation, Good Shepherd Penn Partners, and both CHOP and UPENN's Institutional Review Board.

Once your personal health information is disclosed to others outside of CHOP and UPenn, it may no longer be covered by federal privacy protection regulations.

The Principal Investigators or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the University of Pennsylvania use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study. To take back your permission, you must tell the investigator in writing:

Laura Prosser, PT, PhD
Department of Physical Therapy
The Children's Hospital of Philadelphia
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions about the study, call the CHOP study investigator, Dr. Laura Prosser at 215-590-2495. You may also talk to your own doctor if you have any questions or concerns.

Additionally, should you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania and The Children's Hospital of Philadelphia to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date