

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Title of Project: Monitoring of Activity in Infants

Principal Investigator(s): Michele Lobo, PT, PhD

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you agree to participate.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to enhance our understanding of the activities young infants experience throughout their day and to see if/how this relates to the development of future milestones like crawling and walking. The first aim is to determine whether a garment, the Get Around Garment, that tracks infants' movement activity is feasible for families to use and whether the information it provides is accurate. The second aim is to see what the movement activity of young babies is like. The third aim is to determine whether parent education impacts babies' activity or development.

Your baby will be one of approximately 50 participants in this study. You are being asked to participate because your baby may be under 6-months-old and not yet rolling. To be included in this study, you and your baby must be able to safely and independently engage in the activities and be available for in-person visits. Your baby should not participate in this study if s/he has any restrictions on movement, significant visual impairment, or medical equipment that would restrict movement and play.

WHAT WILL YOU BE ASKED TO DO?

As part of this study you will be asked to meet with 1-2 research team members at a location that is easiest for you (your home, your child's daycare or school, our university facilities) for a total of 5 visits of 30-75 minutes in duration each spread out between the time you enroll (at 1-5 months of age) through 12 months of age. You will also be asked to allow research team members to contact you monthly to collect information about your baby's milestones until your baby walks independently, typically between 10 and 18 months of age.

If you agree to participate, you will first be asked to complete a Health & Demographic Form (5 minutes).

Then, we will meet with you for the first visit (75 minutes) where your baby will wear the Get Around Garment and will be video recorded. The garment is a typical onesie with a soft attached belt with a vinyl pocket that holds a sensor that can track your baby's movement activity (see figure to the right). The small sensor is held in a pocket on the side of the garment so your baby should be comfortable in different positions and you should be able to hold your baby without difficulty. The sensor and video will record your baby's



movement during brief movement activities where the researcher will hold your baby in different positions (on the stomach, on the back, upright). We will also aim to record about 60 minutes of your typical interaction with your baby. This is meant to capture whatever is your usual activity for the time we schedule. For instance, it may involve you holding your baby, placing your baby in a seat while you do chores, or playing with your baby. Our goal is to better understand how the garment captures everyday activity for babies.

After the first visit, we will leave the garment with you and request that you have your baby wear it across 2 days during times your baby is awake and with an adult. We will leave 2 garments just in case one gets dirty. You can wash the garments as you would your typical clothing except that you should first remove the sensor unit. Your baby should not wear the belt with sensor unit when sleeping or not supervised. We will ask you to complete a check log about when your baby had the sensor on.

After 2 days, we will return for the second visit (45-60 minutes). We will collect the garment and wearing log from you and will ask you to complete a 5-minute Garment Perception Survey to learn your thoughts about the comfort, fit, and other characteristics of the garment so we can improve it if needed. We will test your baby using two different brief standardized developmental assessments that look at movement, thinking, and language. We will share the results with you. We will also provide you with education about your baby's development and ask that you engage in activities related to this education for 20 minutes daily for the next 4 weeks. There will be two types of education provided in this study. You will be randomly assigned to receive one of the two types. We want to see if different types of education about development are similarly effective. The activities for both types of education should be fun for you and your baby and aim to easily fit into what is already your typical routine. We will ask you to briefly log your activities daily. It is okay to miss some days but the more days you can do the play activities, the better.

After the 4-week activity period, we will visit you again. We will collect your activity log and repeat the activities from the first visit described above. After another 2-day garment wearing period, we will return for the fourth visit that will repeat all activities from the second visit described above, except you will not receive education again. After the 4-week activity period, daily activity engagement is no longer expected. We will now provide you a list of upcoming developmental milestones and will teach you how to keep track of your baby's milestones. We will contact you monthly until your baby starts walking (typically between 10-18 months of age) to gather this information from you. We can contact you via a method that is easiest for you, such as phone, skype, or email.

When your baby is 12 months old, we will have a final visit where we repeat the developmental assessments for your baby related to movement, thinking, and language. We will again share those results with you.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Possible risks of participating in this research are minimal. The assessment procedures are safe, and are similar to movement activities experienced by babies on a regular basis. The measurements are non-invasive, play-based, and have been used in past research with infants.

There is a risk that your baby may get tired or fussy during the visits. Our team is experienced in working with young babies. We are quite flexible. If your baby cries or shows facial expressions suggesting upset or

fatigue, we can take a break to try to meet your baby's needs. We can reschedule a visit if feeding, a diaper change, or cuddling don't fix the problem.

There is a risk the garment may feel uncomfortable for your baby. For comfort, we designed the garment with the sensor on the side of the torso where babies do not typically place weight before they begin rolling over. Your baby will not be enrolled in the study if s/he is already rolling. In addition, the sensor is quite small (2.44" long x 1.47" wide x 0.7" thick) so is not likely to be uncomfortable or interfere with you carrying your baby. We will also be sure to check your baby's skin for redness after removing the garment. If we notice irritation or redness, we will work on better fitting the garment and sensor. If the problem persists for your baby, we will discontinue that part of the testing.

The sensor unit is made of small parts and uses a low level battery for energy supply. These parts could cause a choking risk if exposed. Therefore, we designed the garment so that the sensor unit is secured within a 3D printed case, which is then housed within a snug fabric enclosure to prevent small parts of the sensor unit from breaking off. As an added precaution, we request that the garment be used only under the supervision of a responsible adult when we leave it with you in the home.

WHAT IF YOU ARE INJURED DURING YOUR PARTICIPATION IN THE STUDY?

If you are injured during research procedures, you will be offered first aid at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document, you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

WHAT ARE THE POTENTIAL BENEFITS?

You and/or your baby may benefit from receiving education about development and learning the results of your baby's developmental assessments. The information gathered in this project can help us better understand the relationships between early activity and future development and how we might change early activity to positively impact future outcomes.

NEW INFORMATION THAT COULD AFFECT YOUR PARTICIPATION:

If during the course of this study we learn new important information that could cause you to change your mind about participating in the study, we will notify you as soon as possible.

HOW WILL CONFIDENTIALITY BE MAINTAINED? WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

We will make every effort to keep all research records that identify you or your child confidential to the extent permitted by law. Confidentiality will be protected by assigning each participant an identification

number (ID) for data storage, sharing, and analysis. An electronic file with this information will be stored on an external hard drive that is kept in a lockable cabinet or on a password-protected computer in a lockable lab. All electronic files, including video recordings, will be stored on external hard drives that are kept in a lockable cabinet in a lockable lab. Videos will be identified by you or your child's study ID number and date of the session. All paper records will be kept in a lockable cabinet. The keys to all locked cabinets used will be kept in a password-protected key box located in a lockable lab.

Video recordings and images of you or your child will not be presented or shown in any way unless you provide permission to do so (see optional consent below). In this instance, identifying information about you or your child will not be disclosed. However, you or your child may be identifiable through the images and accompanying sound recording.

The research team processing and analyzing the data will not identify you or your child by name, and data will be identified by ID number. In reporting the results in publications and presentations, you or your child's name and personal identifying information will not be used.

Your research records may be viewed by the University of Delaware Institutional Review Board, which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. Records relating to this research will be kept for at least three years after the research study has been completed. After 3 years from the completion of the study, all files with your identifying information will be erased or shredded.

We also must let you know that if during your participation in this study our research team was to observe or suspect, in good faith, child abuse or neglect, Delaware state law obligates us to report it to the appropriate officials.

WILL THERE BE ANY COSTS TO YOU FOR PARTICIPATING IN THIS RESEARCH?

There are no costs associated with participating in the study.

WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATION?

There is no monetary compensation for participation in the study. The research team is grateful for you and your baby's participation and time.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your decision to stop participation, or not to participate, will not influence current or future relationships with the University of Delaware or the Early Learning Center if your baby attends one of their centers.

The researchers may choose to terminate your baby's participation in this study, if after several attempts to engage in the activities, your baby does not appear to enjoy them, if new information suggests you or your

baby cannot safely and independently engage in the data collection activities, if you or your baby is not available for in-person data collections or it is not possible to match schedules with that of the experimenters.

If, at any time, you decide to end your participation in this research study, please inform our research team by telling the investigator(s).

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have further questions about this study or its procedures, please contact the principal investigator of the project, Michele A. Lobo, PhD, PT, malobo@udel.edu, 302-831-8526, or the lead researchers Iryna Babik, PhD, ibabik@udel.edu, and Andrea B. Cunha, PhD, andreabc@udel.edu, (302) 831- 8666; Move to Learn Innovation Lab, Department of Physical Therapy; 118 STAR Health Sciences Campus; 540 South College Avenue; University of Delaware; Newark, DE 19713.

If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at hsrb-research@udel.edu or (302) 831-2137.

Your signature on this form means that: 1) you are at least 18 years old; 2) you have read and understand the information given in this form; 3) you have asked any questions you have about the research and the questions have been answered to your satisfaction; and 4) you accept the terms in the form and volunteer to participate in the study with your baby. You will be given a copy of this form to keep.

Printed Name of Parent/Guardian

Signature of Parent/Guardian

Date

Person Obtaining Consent

Person Obtaining Consent

Date

(PRINTED NAME)

(SIGNATURE)

Printed Name of Participating Infant

OPTIONAL CONSENT FOR ADDITIONAL USES OF VIDEO RECORDINGS/PHOTOGRAPHS

I voluntarily give my permission to the researchers in this study to use videos and photographs of my baby and me collected as part of this research study for publications, presentations, and/or educational purposes. I understand that no identifying information beyond that contained in the video recording will be provided to educational/scientific audiences; however my facial features and those of baby may be seen.

Signature of Parent/Guardian

Date

Printed Name of Parent/Guardian

OPTIONAL CONSENT TO BE CONTACTED FOR FUTURE STUDIES:

Do we have your permission to contact you regarding participation in future studies? Please write your initials next to your preferred choice.

_____ YES

_____ NO