

Consent Excellence: Integrating Health Literacy into Research

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Background

- Informed consent is key to ethical research. Limited health literacy can impact the ability to fully comprehend the information within research consent forms (Tamariz et al., 2013).
- In 2018, Children's Mercy's launched Consent Excellence Project to address and eliminate barriers to informed consent. The Director of Research Integrity became a Health Literacy Advocate to connect Health Literacy to these efforts.
- The Health Literacy Committee was included with six essential stakeholder groups within Children's Mercy, including the Health Literacy Program Manager joining the Consent Excellence Task Force.

Tamariz, L., Palacio, A., Robert, M., & Marcus, E. (2013) Improving the Informed Consent Process for Research Subjects with Low Literacy: A Systematic Review. Journal of General Internal Medicine. DOI:10.1007/s11606-012-2133-2

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IRB Effective Date: 12/19/2019

Children's Research Institute
CHILDREN'S MERCY KANSAS CITY


Weigh Easy: Simplifying Home Weight Monitoring for Infants

Who to contact?


 **If an emergency, call 911**

Call if you think your child is sicker or has suffered injury of any kind as a result of being in this study:

Katie Shedd, PA-C, MSPAS (913) 696-2573
Or
Meghan Tracy (816) 302-2220

 Call if you have questions about the study or any information in this consent form:

Katie Shedd, PA-C, MSPAS (913) 696-2573
Or
Meghan Tracy (816) 302-2220

 Call if you have questions about your and your child's rights, or have any concerns or complaints:

Children's Mercy Institutional Review Board

KEY INFORMATION

Why do we want to talk to you about joining this study?

We're asking you and your baby to join this study because your baby has a cleft lip and/or cleft palate (CLP). Babies born with CLP sometimes have problems gaining weight after they are born.

The purpose of this study is to see if the Weigh Easy system is an easier way for parents to collect and report weights for babies with CLP. The Weigh Easy system has not been fully tested before. This will help see if it is easier than other ways to measure weight.

What will you be asked to do?

We ask you to weigh your baby at home 1 time each week for 3 months with the Weigh Easy system. You will then enter your baby's weight on a website or mobile app. You will be asked to take a survey at the end of the study to tell us if you liked the Weigh Easy system or not.

What are the main risks and benefits?

The Weigh Easy system uses a luggage scale to weigh your baby in their car seat. We hope that the use of the Weigh Easy system will give us better information about your baby's weight. This may help us treat your baby better. There is a risk that you could drop the car

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Methods

An initial study called the **Weigh Easy Program** was identified to draft and pilot this new consent form format. It was streamlined to include:

- The most important information about the study at beginning.
- Simplified language to reduce confusion and anxiety.
- Added multiple pictures
- Integration of teach back in the consent process and to ensure parental use of equipment.

Outcomes

This project established a precedence of including health literacy to create a more understandable research consent form and processes by:

- limiting medical jargon
- incorporating more lay terms
- making the form easier to navigate with pictures and information chunking
- Integrating teach back

This serves as a model for other departments and research coordinators.