

Research Consent /Authorization Form/ Parental Permission

IRB #2020-0207

Study Name: ENCIRCLE

Full Title: Patient-Clinic-Community Integration to Prevent Obesity Among Rural Preschool Children

Site(s): Geisinger Community Medicine Service Line, Geisinger Pediatric Clinics

Funded by: Patient-Centered Outcomes Research Institute (PCORI)

In this consent form, “you” always refers to the person taking part in the research study. If you are a parent or guardian, “you” refers to the person taking part in the research study.

We are asking you to be in a health research study.

You do not have to be in this study. Your access to care at Geisinger will not change if you say no. If you join this study, you can stop at any time.

This form tells you about the study and how your health information will be used.

What Should I do?

- Read this form or have it read to you.
- Make sure we explain the study to you.
- Make sure we explain what is done for research and what is done as part of your routine care.
- Ask questions.
- Take time to think about this and talk to your family and friends.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

During the study, we will tell you if there is new information or changes to the study that could affect you, your health or your desire to stay in the study.

Why is this study being done?

We are asking you to join this study because you receive care at a participating Geisinger clinic location. We want to learn more about how best to improve well-child visits for children to promote healthy lifestyles.

Who will be in the study?

About 2,025 people will join at Geisinger.

How long will I be in the study?

You will be in the research study for about one year.

What will I be asked to do?

You will be asked to attend the regular well-child visits with your child. You already schedule and attend these visits. You will also be asked to complete surveys. You may be contacted via text message reminding you to complete surveys and other study-related items. You may be asked to join in telephone calls with a health coach. There will be 1 call a month for 6 months. Some calls may be recorded for training and monitoring purposes. You may also be invited to a local grocery store tour with a nutritionist. The grocery store tour will also be offered virtually.

Will I be paid?

If you choose to participate in this research study, you will receive up to \$200 in checks for completing surveys. These surveys will happen at the start of the study and 6 and 12 months later. For each completed survey you will receive a \$50 check. If you complete all 3 surveys, you will receive an additional \$50 check.

Your check will arrive in the mail up to 8 weeks after we receive your completed survey.

Can being in this study help me?

This study might or might not help you. We hope that what is learned from this study will help others in the future. Your participation may help researchers to develop better ways to care for children.

What are the risks?

There are no physical risks expected with this study. There is a risk that your information could be seen by someone other than the study staff. However, we will take steps to protect your information.

You or your insurance will be charged for the diagnosis and treatment of any injury that results from your routine care.

How will Geisinger use and share my information?

The Geisinger study staff will view and collect information that is in your child's medical record. We will collect information about your child during this study. Some of this information will be kept in a research record at Geisinger. These records will be kept indefinitely. Any information placed in your child's medical record will be a permanent part of your child's medical record.

By signing this form, you are giving Geisinger permission to use and share your child's health information. It can be shared indefinitely for purposes of this research study, as explained in this form. If you change your mind, tell us in writing to stop using and sharing your child's information. Information already collected will still be used. We will only use and share new information if it is needed to protect your child's safety or follow with the law.

Write to: ENCIRCLE

How will others use and share my information?

Your child's research and medical record could be reviewed for quality and to make sure rules are followed. This review could be done by:

- Geisinger Institutional Review Board
- Geisinger staff
- The Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS)
- Office for Human Research Protections (OHRP)
- PCORI

If information from this research study is included in an article published in a medical journal or presented at a medical or scientific meeting, it will be done in a way that does not identify your child. If information from this study is shared with research partners external to Geisinger, it will be done in a way that does not identify your child.

How is my information protected?

We will take steps to protect your child's information. All information collected as part of this research study will be kept on the Geisinger network, which is password-protected and only accessible to approved study staff. Your child will also be assigned a unique study identifier which will be used to identify your child in the study. This identifier will be used in place of your child's medical record number. Some laws that protect your child's information only apply to hospitals, doctors' offices, and other

healthcare providers. When your child's information is shared outside of Geisinger some federal privacy laws might not apply.

We will share your child's information with a court of law or the government, in the unlikely event this is required.

What if I have questions or problems?

Call: ENCIRCLE Study if you:

- Have questions, concerns or complaints about the study
- Feel you have had a study-related injury

Call the Geisinger Institutional Review Board (IRB) at:
844-542-3299 or 570-271-8663 (Danville, PA)

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.

Signature Section

Research Participant's Printed Name

Parents/Guardians:

I give permission for my child to take part in this research study and allow their health information to be used for this research. My questions have been answered. I will get a signed copy of this form.

Print Name of Parent/Guardian

Signature of Parent/Guardian

Date