DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
ADULT
Pilot Adaptive Tool To Encourage Risk reduction in iNfancy (PATTERN)

CONCISE SUMMARY

The purpose of this research study is to learn about different approaches to promoting healthy growth among infants, and understanding parents' likes and dislikes of an approach to reducing risk factors for obesity later in life. The study includes filling out some forms with questions about your baby and your thoughts about your baby's growth and health, and engaging in a pattern of changes in or prevention of risk factors in the first year of life. Parents will receive information about changes and some tools and materials to take home with them. Some parents may receive phone calls between visits as well. The study takes place from soon after birth through the infant's age of 9 months. The estimated total time of interaction between the study staff and parents during the study period is 4 hours.

The greatest risks to this study would be feeling uncomfortable about answering some of the questions.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you have an infant. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Wood will conduct the study and it is funded by the REACH Equity Center at Duke. The Center will pay Duke University to perform this research and will pay some of Dr. Wood's salary.

WHY IS THIS STUDY BEING DONE?
The purpose of this research study is to learn about different approaches to promoting healthy growth among infants, and understanding parents' likes and dislikes of an approach to reducing risk factors for obesity later in life.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 40 people will take part in this study at Duke clinics.

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WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will be asked to fill out some questionnaires and take home some materials that encourage preventing risk factors for your infant. We will continue to contact you around the time of the next few well child visits for your infant and potentially phone calls in between visits. We will ask you to complete a questionnaire on the day you sign up, and at two follow-up visits within the first 9 months of your infant's life. You may refuse to answer any questions or stop your participation at any time. We will also gather some information about your baby's growth from their medical record.

HOW LONG WILL I BE IN THIS STUDY?
The study will last from the first visit your baby has through when your baby is about 9 months old. Each contact with the study team should last not more than 30 minutes, and the estimated total time should be no more than 4 hours. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. Your baby's growth will be monitored by your baby's physician and our research team. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this can not be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there will be no direct medical benefit to you. We hope that in the future the information learned from this study will benefit other parents as they raise their children.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating on the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the Duke University Health System Institutional Review Board and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

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The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $20 for your expenses related to your participation to compensate for time taken to answer questionnaires and listen to messages related to risks. The total reimbursement you can receive is $60 for the entire length of the study, for completing the initial questionnaire and the two follow-ups.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Charles Wood at 919-620-4772 during regular business hours and at 919-970-7037 after hours and on weekends and holidays.

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Wood in writing and let him know that you are withdrawing from the study. His mailing address is 4020 N. Roxboro St. Durham, NC, 27704.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Clinical Trials Registry:
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. This study is listed under ClinicalTrials.gov Identifier: NCT04216264

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Wood at 919-620-4772 during regular business hours and at 919-970-7037 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time