Document Coversheet

Study Title: Communities Helping the Hearing of Infants by Reaching Parents: The CHHIRP Navigator Trial

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KEY INFORMATION FOR: Communities Helping the Hearing of Infants by Reaching Parents: The CHHIRP Navigator trial (Parent Participants – Aim 2)

You are being invited to take part in a research study about patient navigation and infant hearing.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

The purpose of this study is to test a patient navigation program to improve the effectiveness of infant hearing testing throughout Kentucky. We will train community navigators to provide education and resources to parents of infant to help them get their infant's hearing testing in a timely fashion. This study evaluates (1) whether patient navigation in state-funded clinics throughout Kentucky increases parents' follow-through with testing, (2) factors that promote or impede its delivery, and (3) cost-effectiveness of this approach. By doing this study, we hope to learn if this program is feasible to deliver and is acceptable to both the parents trained as navigator to deliver the program and to the parents who participated in the study. In this study, you will meet with a member of the study staff one time during the study to complete questionnaires and participate in an interview. Your participation in this research will last about 1-2 hours.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Your willingness to volunteer may help develop a program that could better address hearing loss in children. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You should not volunteer if you do not wish to perform the duties expected as a parent to an infant selected for the study, or complete the examination, questionnaires, or the interview process. For a complete description of risks, refer to the Detailed Consent.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Matthew Bush, MD, PhD of the University of Kentucky, Department of Otolaryngology. There may be other people on the research team assisting at different times during the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, contact information for Dr. Bush is: 859-257-5097 or matthew.bush@uky.edu.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You will not qualify for this study if you are not a resident of the state of Kentucky for the entire period of the study.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will take place at a location agreed upon by you and study personnel. For example, via phone, your place of employment, a library, or some other mutually agreed upon location. The overall study process for parent participants in this part of the study (Aim 2) should take no longer than the time required for answering questionnaires and submitting to a one-hour interview.

WHAT WILL YOU BE ASKED TO DO?

When you meet with the study staff, the interviewer will ask you several questions and invite you to share your thoughts. At the Aim 1 post-test assessment (16 weeks post-birth), parents will complete a PN satisfaction measure. Selected parents (about 40) will also complete a 1-hour semi-structured interview exploring parents' experiences with the PN intervention. The interview will be audio-recorded so that we are sure to keep good records of all of your answers. Some questions will be in the form of a written questionnaire rather than an interview.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The primary risk associated with this study is loss of confidentiality. A breach of confidentiality may involve a risk to your employment or your professional or personal relationships. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, your willingness to take part may help improve the delivery of patient navigation for families of infants who need hearing testing follow up and allow more families to be able to access such a program in the future.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in this study, other than possible costs of transporting yourself to the interview site.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify you to the extent allowed by law.

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. We will also be using REDCap to collect and store data for this study. REDCap is a secure web platform for building and managing online databases and surveys. Only members of the study team will be granted access to the REDCap database. Electronic or written information identifying you as a research participant will be stored using identification numbers rather than your names or other identifying information, and computer files containing your information will be password-protected and accessible only to the research team.

You should know that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with a court or authorities if you report information about you or your child being abused or if you pose a danger to yourself or someone else. Officials of the University of Kentucky may look at or copy pertinent portions of records that identify you.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

If you decide to take part in the study, you still have the right to decide at any time that you no longer want to continue. You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

The investigator conducting the study may need to remove you from the study. This may occur if you are not able to follow the directions, if he finds that your participation in the study is more risk than benefit to you, or if the sponsor of the study chooses to stop the study early for a number of scientific reasons. If you withdraw or are withdrawn from the study, data collected until that point will remain in the study database and may not be removed.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator know if you are in another research study. You should discuss this with the investigator before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Matthew Bush at 859-257-5097.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility, **or** may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); **or** may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.). A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

Parents completing post-test measures will be compensated $20 under Aim 1, and parents completing interviews for the Aim 2 part of the study will be compensated an additional $25.

WHAT ELSE DO YOU NEED TO KNOW?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Note: The funding for this study was made possible by an R01 grant awarded to Dr. Bush by the National Deafness and Other Communication Disorders (NDCD) Advisory Council and the National Institutes of Health (NIH). The NDCD advises the NIH on research opportunities deemed worthwhile and in need of financial support.

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POTENTIAL FUTURE USE OF YOUR INFORMATION:

Your information collected for this study will NOT be used or shared for future research studies. However, we do request to retain your contact information in order to contact you regarding potential participation in additional research studies related to hearing loss in children.

Do you give your permission to be contacted in the future by this research team regarding your willingness to participate in future studies about hearing loss in children?

☐ Yes ☐ No _____Initials

INFORMED CONSENT SIGNATURE

You are a participant or are authorized to act on behalf of the participant. This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____ _____
Signature of research subject Date

_____
Printed name of research subject

_____ _____
Printed name of [authorized] person obtaining informed consent Date