Document Coversheet

Study Title: Behavioral Parent Training for Families With Deaf and Hard of Hearing Preschoolers

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Norton Children's ENT & Audiology
Affiliated with UL SCHOOL OF MEDICINE

KEY INFORMATION FOR: Behavioral Parent Training for Families with Deaf and Hard of Hearing Preschoolers (Parents/Caregivers and Children – Aim 4)

You and your child are being invited to take part in a research study about the effectiveness of a parent coaching program to support parents of young children who are deaf and hard of hearing and who use hearing devices.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study (known as "CHAMPS-DHH") is to evaluate the effectiveness of an established parent coaching program, the "Family Check-Up" (FCU), which we have specifically adapted for use with parents of children who are deaf and hard of hearing and who use hearing devices (hearing aids, cochlear implants, and/or bone conduction devices). By doing this study, we hope to learn if this program is feasible to deliver, if it is acceptable to the parents trained as coaches to deliver the program, if it is acceptable to the parents who receive the program, and if it helps parents use effective positive parenting strategies. We are also interested in whether being in the program helps improve children's behaviors, helps children use their hearing devices more consistently, and helps improve children's speech and language over time. In this study, over the course of 3 years, or until the study ends:

- you will complete questionnaires about you and your child at up to 7 different time-points spaced about 6 months apart;
- starting next year, your child will participate in video-recorded, online speech and language assessments with our trained study staff at up to 3 different time-points about 12 months apart;
- you and your child will do short video-recorded tasks at up to 4 time-points about 12 months apart;
- with your permission by signing this form, your child's hearing healthcare provider will provide us with information about your child's hearing treatment; and
- about half of parents will be randomized to a group that will receive the FCU parent coaching program, and if you are in that group, you will complete up to 18 online or phone-based parent coaching sessions with a trained parent coach (up to 6 per year for up to 3 years).

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

Your willingness to volunteer may help develop a program that could better address some behavioral challenges experienced by parents of young children who are deaf and hard of hearing and who use hearing devices. For a complete description of benefits, refer to the Detailed Consent.

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

You should not volunteer if you do not wish to complete questionnaires about you and your child; if you do not want your child to participate in speech and language evaluations; if you do not wish for your hearing healthcare provider to provide data from their records regarding your child; or if you do not wish to participate in videotaped sessions. 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?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, contact the research project director, Julie Jacobs of the University of Kentucky, Department of Otolaryngology at 859-218-2018 or julie.jacobs@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 younger than 18 years old; you are not the custodial caregiver of a child between the ages of 3 and 6 years old (at first contact) who is deaf or hard of hearing and who has worn a hearing device for at least 6 months; that child does not live in your home the majority of time; you have already accessed behavioral health services for that child; you are involved in an active child protective services case; or you cannot communicate in either English or American Sign Language.

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

The research procedures will be conducted remotely (by videoconferencing, by telephone, by online survey, or by mail). You and your child will be involved in the study for up to 3 years.

At the beginning of the study, you will complete a set of questionnaires about you and your child which will take about 1 ½ to 2 hours to complete (later referred to as the "annual" questionnaires). They can be emailed or mailed to complete on your own, or you can complete them with research staff over the phone if you prefer. Additionally, you and your child will participate together in brief tasks that assess specific parent-child interactions. These tasks will be recorded remotely by secure videoconferencing software (for example, Zoom). Your child's participation in these tasks will last approximately 30 minutes. Your total participation in this first set of assessments will last approximately 2 - 2 ½ hours.

About half of the families involved in this study will be randomly assigned (like flipping a coin) to receive the FCU parent coaching program in addition to completing the assessments described in the paragraph above (i.e., the "intervention" group). The other half of parents/children will only complete the assessments but will not receive the parent coaching program (i.e., the "control" group). Your assignment to either the "intervention" or "control" group will be randomly assigned after you complete the first set of assessments. <u>You will not know which group you will be in until after the first set of assessments are completed.</u>

If you are in the "intervention" group that receives the FCU parent coaching program, about one week after your first set of assessments are completed, you will meet by videoconference or by phone with a trained parent coach for your first FCU parent coaching session. FCU sessions consist of a 60-minute assessment session, completion of a questionnaire following the first session, a 45-minute feedback session, and up to four optional 60-minute skills training sessions. Sessions will occur annually (up to 6 sessions per year) over a 4-month period for each of the 3 years you are in the study. Portions of these sessions may be videotaped to assess the coach's delivery of the session. The coach will ask for your permission and will tell you when videotaping begins and ends. During these sessions, other family members who want to may appear in the video if they attend that session and provide consent.

Next, parents in both the "intervention" and "control" groups will complete a "mid-year" set of questionnaires (either online, by mail, or by phone) six months after the first set of assessments. The time required to complete these questionnaires will be approximately 15-30 minutes.

One year after you start the study, you will repeat most of the "annual" questionnaires (about 1 - 1 ½ hours, either online, by mail, or by phone). Additionally, you and your child will record the videotaped tasks again (about 30 minutes), and your child will complete several speech and language assessments in an online session with trained study staff (about 1- 1 ½ hours). You will be asked to assist during some portions of the child's assessment. Total participation in this appointment will last about 2 hours for both you and your child. If you are in the "intervention" group, you will meet virtually with the trained parent coach again and have the opportunity to complete up to 6 remote sessions of the FCU. Parents in both the "intervention" and "control" groups will repeat the "mid-year" set of questionnaires (about 15-30 minutes, either online, by mail, or by phone).

Two years after you start the study, you will repeat the same activities as the previous year ("annual" and "mid-year" questionnaires, plus the FCU sessions if you are in the "intervention" group). At the end of that year (or 3 years after you began the study), you will also repeat the "annual" questionnaires, you and your child will repeat the videotaped tasks, and your child will repeat the speech and language assessments. A full schedule is shown in a table on the next page. Your participation may end before 3 years if the study ends before that time. The research team will keep you updated on the anticipated study end date.

TIMELINE FOR "INTERVENTION" GROUP:

Time Point	Activity	Parent Involvement	Child Involvement
Starting the study	• Parent "annual" questionnaires • Parent and child videotaped tasks	2 – 2 ½ hours	About 1/2 hour
	FCU Parent Coaching Sessions (scheduled over next 12 weeks)	Up to 6 hours in 6 sessions	-
6 months later	• Parent "mid-year" questionnaires	1/2 hour	-
1 year later	• Parent "annual" questionnaires • Parent and child videotaped tasks • Child speech and language assessments	1 ½ - 2 hours	About 2 hours
	FCU Parent Coaching Sessions (scheduled over next 12 weeks)	Up to 6 hours in 6 sessions	-
1 ½ years later	• Parent "mid-year" questionnaires	1/2 hour	-
2 years later	• Parent "annual" questionnaires • Parent and child videotaped tasks • Child speech and language assessments	1 ½ - 2 hours	About 2 hours
	FCU Parent Coaching Sessions (scheduled over next 12 weeks)	Up to 6 hours in 6 sessions	-
2 ½ years later	• Parent "mid-year" questionnaires	1/2 hour	-
3 years later	• Parent "annual" questionnaires • Parent and child videotaped tasks • Child speech and language assessments	1 ½ - 2 hours	About 2 hours

TIMELINE FOR "CONTROL" GROUP:

Time Point	Activity	Parent Involvement	Child Involvement
Starting the study	• Parent "annual" questionnaires • Parent and child videotaped tasks	2 – 2 ½ hours	About 1/2 hour
6 months later	• Parent "mid-year" questionnaires	1/2 hour	-
1 year later	• Parent "annual" questionnaires • Parent and child videotaped tasks • Child speech and language assessments	1 ½ - 2 hours	About 2 hours
1 ½ years later	• Parent "mid-year" questionnaires	1/2 hour	-
2 years later	• Parent "annual" questionnaires • Parent and child videotaped tasks • Child speech and language assessments	1 ½ - 2 hours	About 2 hours
2 ½ years later	• Parent "mid-year" questionnaires	1/2 hour	-
3 years later	• Parent "annual" questionnaires • Parent and child videotaped tasks • Child speech and language assessments	1 ½ - 2 hours	About 2 hours

WHAT WILL YOU BE ASKED TO DO?

If you are in the "intervention" group, you will complete up to 7 sets of questionnaires; you and your child will complete up to 4 sets of videotaped tasks; your child will have up to 3 in-person meetings with our study staff to complete speech and language assessments (starting one year after you begin the study); and you will participate in up to 18 parent coaching sessions. Your total time commitment is estimated to be up to about 26-28 hours over 3 years. Your child's total time commitment is estimated to be about 6-7 hours over 3 years.

If you are in the "control" group, you will complete up to 7 sets of questionnaires; you and your child will complete up to 4 sets of videotaped tasks; your child will have up to 3 in-person meetings with our study staff to complete speech and language assessments (starting one year after you begin the study). Your total time commitment is estimated to be about 8-10 hours over 3 years. Your child's total time commitment is estimated to be about 6-7 hours over 3 years.

For all participants, the questionnaires completed by you throughout the study will ask about you and your child, including background questions about you and your child, questions about your child's behavior, questions about family relationships, questions about your well-being, and questions about your feelings about parenting. One portion of each annual assessment session will involve a brief, video- or audio-recorded interview. One year after you start the study, your child's annual speech and language evaluations will be conducted online with a trained member of our research staff and will involve asking your child questions, showing your child pictures, or having your child listen for sounds. Your child's assessment will be video-recorded. Additionally, you and your child will participate together once per year in up to 4 brief video-recorded tasks that assess specific parent-child interactions.

If you are part of the "intervention" group that also receives the FCU parent coaching sessions, those meetings with a parent coach will consist of discussions, questionnaires, coaching, and feedback about parenting. Portions of these sessions may be video-recorded to determine the quality of the coach's delivery of the session. The coach will ask for your permission and will tell you when videotaping begins and ends. During these sessions, other family members who want to may appear in the video if they attend that session.

We will also ask for alternative methods to contact you in case your current contact information changes and we cannot locate you for follow-up appointments. Providing this information is optional, and you may choose which pieces of information to share. If you are signing this document online, you will be asked to complete this section at the end of the form.

Do you wish to provide additional contact information for yourself and/or for relatives or friends that may help us locate you if we become disconnected?

☐ Yes ☐ No _____Initials

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The primary risk associated with this study is loss of confidentiality. You may experience some discomfort in talking about child behavior problems or family relationships. If you are in the "intervention" group and decide to try new parenting strategies based on the information you learn during the parent coaching sessions, your child's behavior may change for either the better or the worse. The parent coaching sessions are delivered by a trained and supervised parent coach, and not by a mental health professional. 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?

Research is designed to benefit society by gaining new knowledge. Your participation, whether you are in the "intervention" or "control" group, will help evaluate the effects of a parent coaching program for families with young children who are deaf or hard of hearing and who use hearing devices. The results of this study may allow more families to be able to access such a program in the future, if it is found to be effective. Also, after your annual assessments, we will provide you with a summary of your child's progress in language assessments, compared with the previous year's assessments. We do not know if you will get any personal benefit from taking part in this study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs to participating in this study, other than possible costs of connecting to online or telephone appointments. You will be responsible for your own telephone/internet fees. If we are aware prior to the appointment, our research team can work to find solutions that will not result in extra charges for you.

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you or your child may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify you and your child 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, your child's 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. Electronic or written information identifying you and your child as research participants 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. To ensure the study is conducted properly, officials of the National Institutes of Health and/or the University of Kentucky may look at or copy pertinent portions of records that identify you.

We will make every effort to safeguard your data. REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

Certificates of Confidentiality (CoC):

To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers can use this Certificate to refuse to disclose information that may identify you to anyone not connected with this study, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the sponsor (e.g., National Institutes of Health) or agency auditing the research;
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study.

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 and your child no longer want to continue. You can choose to leave the study at any time. You and your child will not be treated differently if you decide to stop taking part in the study.

The investigators conducting the study may need to remove you from the study. This may occur if you are not able to follow the directions, if they find 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 and your child may take part in this study if you are currently involved in another research study. It is important to let the investigators know if you or your child are in another research study. You should discuss this with the investigators 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 or your child are hurt or if you get sick because of something that is due to the study, you should call Julie Jacobs immediately at 859-218-2018.

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 or your child get hurt or sick while taking part in this study. 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 or your child's care and treatment because of study-related harm will be your responsibility.

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

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

You will receive $75 by mail after you complete the first set of assessments, and $100 after each of the "annual" assessment appointments. You will receive $50 by mail after completing each "mid-year" assessment. At the end of the study, you will receive an additional payment of $100 if you complete all 7 sets of research assessments, an additional $75 if you complete 6 sets of assessments, and an additional $50 if you complete 5 sets of assessments. If you complete the study in its entirety, you may receive up to $625 over a 3 year period; however, those who enroll later in the study will be involved for fewer years (e.g., you could receive up to $425 if the study ends 2 years after you enroll). If you earn $600 or more by participating in research within a single year, it is potentially reportable for tax purposes. With your permission, your child will also be offered a small age-appropriate toy (e.g., stuffed animal, puzzle) following their 3 speech and language assessments to acknowledge their contribution to the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researchers learn of new information in regards to this study, and it might change your willingness to stay in this study with your child, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH ASSESSMENTS?

Generally, assessments done for research purposes are not meant to provide clinical information. There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by Julie Jacobs and other study investigators to determine if it is in your best interest to contact you.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 125 families to do so through the University of Kentucky, University of Louisville, and other partnering institutions. The National Institutes of Health is providing financial support and/or material for this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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.

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. If you are signing this document online, you will be asked to complete this section at the end of the form.

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

☐ Yes ☐ No _____Initials

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your child's health information that may be accessed, used and/or released includes:

- Demographic information; history of prematurity; type, severity, and stability of hearing loss; causes of hearing loss; family history of hearing loss; other medical conditions or developmental conditions as related to this study; medical management and surgical history for hearing loss; age of diagnosis; age of amplification and/or implantation; history of speech and audiological assessments and therapeutic services; and results of speech, language, and hearing assessments

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- UK Hospital;
- National Institutes of Health

The researchers agree to only share your health information with the people listed in this document.

Should your child's health information be released to anyone that is not regulated by the privacy law, your child's health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign this form, it will not affect your:

- Current or future healthcare at the University of Kentucky or other providers;
- Current or future payments to the University of Kentucky or other providers;
- Ability to enroll in any health plans (if applicable); or
- Eligibility for benefits (if applicable).

After signing the form, you can change your mind and NOT let the researcher(s) collect or release your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Julie Jacobs, 740 South Limestone, E300E, Otolaryngology, Lexington KY 40536-0284 to inform her of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

INFORMED CONSENT SIGNATURE PAGE

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 (and child's legal representative) Date

_____
Printed name of research subject (and child's legal representative)

_____
Printed name of child taking part in the study

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