Document Coversheet

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

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	9/19/2025
NCT Number:	NCT03916146
IRB Number	45213
Coversheet created:	10/13/2025

IMPORTANT NOTE:

If you accidentally select the wrong IRB type or "Protocol Process Type" while your Initial Review (IR) application is in draft form (unsubmitted), you may change your selections. Please contact the Office of Research Integrity (ORI) at 859-257-9428, IRBsubmission@uky.edu, or request a consult to resolve any questions regarding your selections *prior* to submitting your Initial Review application.

If your **submitted IR application has been returned to you for requested revisions or additional information,** to streamline the review process **do not make changes** to your selections here **unless instructed to do so by the ORI/IRB.**

Changes to this section cannot be made after initial approval has been issued (the option is not available for MR or CR).

For guidance, see:

- Which IRB should review my research?
- Which Protocol Process Type?
- "Getting Started"

Which IRB

- (•) Medical ( ) NonMedical

Protocol Process Type

- ( ) Exemption
- ( ) Expedited (Must be risk level 1)
- (•) Full

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the Exemption Categories Tool.

MODIFICATION REQUEST SECTION

0 unresolved comment(s)

***** If this modification changes the scope of your activities to include COVID-19 related research, please insert "COVID19" at the start of your Project and Short Titles.*****

Select One:

- (•) This modification does not increase risk to study participants.
- ( ) This modification may or will increase risk to study participants.

Is this modification request due to an Unanticipated Problem/Adverse Event, or Protocol Violation?

( ) Yes (•) No

In your professional opinion, does this modification involve information that might relate to a subject's willingness to continue to take part in the research?

( ) Yes (•) No

If yes, state how the information will be communicated to subjects (i.e., re-consent, send letter, etc.):

For each proposed modification, include a justification.

Example: Jane Doe, MD, is being added as co-investigator because she has expertise with the subjects on this protocol. She has completed human subject protections training, and is authorized to obtain consent.

Aim 5 key stakeholder interviews - consent form, quantitative measures, qualitative interview guide

PROJECT INFORMATION

0 unresolved comment(s)

Title of Project: (Use the exact title listed in the grant/contract application, if applicable).
If your research investigates any aspect of COVID-19, please include "COVID19" at the beginning of your Project Title and Short Title

Behavioral Parent Training for Families with Deaf and Hard of Hearing Preschoolers

Short Title Description
Please use a few key words to easily identify your study - this text will be displayed in the Dashboard listing for your study.

FCU-DHH

Anticipated Ending Date of Research Project: 8/31/2025

Maximum number of human subjects (or records/specimens to be reviewed) 570

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? ◉ Yes ○ No

Are you requesting that the UK IRB serve as the lead IRB for a multi-site study, **OR** that the UK IRB defer review to another IRB? [Click here for "IRB Reliance" help]
◉ Yes ○ No
If "Yes," before completing your IRB application, fill out the Reliance Request Form and submit it to irbreliance@uky.edu.

PI CONTACT INFORMATION

0 unresolved comment(s)

Principal Investigator (PI) role for E-IRB access
The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*).

If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be listed as PI here.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to myUK and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a 'Name Change Form' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the HR Benefits Office for additional information.

The Principal Investigator's (PI) contact information is filled in automatically based on who logged in to create the application.

If you are not the Principal Investigator, do NOT add yourself as study personnel.
To change the PI contact information on an application in Researcher edit status:

- click "Change Principal Investigator";
- search for the PI's name using the search feature;
- click "Select" by the name of the Principal Investigator, then "Save Contact Information".

  You will automatically be added as study personnel with editing permissions to continue editing the application.

Change Principal Investigator:

First Name:	Julie	Room# & Bldg:	E300E Kentucky Clinic
Last Name:	Jacobs	Speed Sort#:	0284
Middle Name	A		
Department:	Otolaryngology - 7H860	Dept Code:	7H860
PI's Employee/Student ID#:	12067307	Rank:	
PI's Telephone #:	8592182018	Degree:	MPH
PI's e-mail address:	JJA233@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	5/7/2024
		RCR Trained:	Yes

Do you, the PI/researcher, have a significant financial interest related to your responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2)?

○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

- (•) (Risk Level 1) Not greater than minimal risk
- ( ) (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- ( ) (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ( ) (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Refer to UK's guidance document on assessing the research risk for additional information.

SUBJECT DEMOGRAPHICS **0 unresolved comment(s)**

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 2yrs to 99yrs

Study Population:

Describe the characteristics of the subject population, including age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- Justification for the inclusion of vulnerable groups such as children, prisoners, adults with impaired consent capacity, or others who may be vulnerable to coercion or undue influence.

Please consider this FDA Guidance on Enrollment of Participants from Underrepresented Populations in Clinical Studies

AIM 1 (CAB) - COMPLETE

In Aim 1, there are no participants. Our CAB members are considered collaborators rather than research subjects. They will provide no personal data for use in publications or other research dissemination efforts.

AIM 2 (ADAPTATION) - COMPLETE

In Aim 2, we will involve two groups of participants: (1) parents/caregivers, and (2) key stakeholders.

(1) Parents/Caregivers: In Aim 2, parents (n = approximately 20) of preschool-aged DHH children will be recruited. Inclusion criteria: (a) age 18 years or older, (b) custodial caregiver of a DHH child aged 3-7 years who uses hearing aid(s) and/or cochlear implant(s), (c) the child lives full-time in the caregiver's home, (d) willing to participate, and (e) able to speak, understand, and read English. Exclusion criterion: (a) active child protective services case, and (b) the child of interest has been diagnosed with a severe developmental condition other than hearing loss (e.g., extreme developmental delay, severe autism, debilitating neurological conditions, etc.), because BPT may not be the appropriate intervention for these families.

(2) Key Stakeholders: During Aim 2, we will identify key stakeholders (n= 15), including approximately equal numbers of hearing healthcare providers, speech and language therapists, and DHH educators. Our anticipated sample size is based on the dual goal of reaching saturation and achieving representation of several different types of providers. Inclusion criterion: the participant must provide services to young DHH children. Exclusion criteria: None.

AIM 3 (PILOT) - COMPLETE

In Aim 3, we will involve two groups of participants: (1) parents and their DHH child, and (2) interventionists (i.e., "parent coaches").

(1) Parents/Caregivers and Children: In Aim 3, parents (n=2) and their target DHH children (n=2) will be recruited. Inclusion criteria: (a) parent/caregiver is age 18 years or older and the custodial guardian of the DHH child, (b) the child is 2-5 years old, (c) the child is DHH and has used hearing aid(s) and/or cochlear implant(s) for >6 months, (d) the child lives full-time in the parent/caregiver's home, (e) the parent/caregiver is willing to participate, and (e) the parent/caregiver is able to read English and either speak/understand English or use American Sign Language. Exclusion criterion: (a) active child protective services case, and (b) the child of interest has been diagnosed with a severe developmental condition other than hearing loss (e.g., extreme developmental delay, severe autism, debilitating neurological conditions, etc.), because BPT may not be the appropriate intervention for these families, (c) the parent has already accessed behavioral health services for the child, and (d) the parent participated in Aim 2 of the study.

(2) Interventionists ("parent coaches"): In Aim 3, parent representatives (n=2) of Hands & Voices, a non-profit organization dedicated to supporting families with DHH children, will be recruited as interventionists. Inclusion criteria: (a) age 18 years or older, (b) parent of a DHH child, and (c) able to speak, understand, and read English. Exclusion criteria: none.

AIM 4 (EFFECTIVENESS)

In Aim 4, we will involve two groups of participants: (1) parents and their DHH child, and (2) students who will conduct a scoring task

(1) Parents/Caregivers and Children: In Aim 4, parent-child dyads will be recruited from hearing healthcare practices and other organizations that support DHH children and their families in the United States (n=125 dyads). Inclusion criteria: (a) parent is age 18 or older and the custodial guardian; (b) child is aged 3-6 and lives majority of the time in the parent's home; (c) child is DHH and has used a hearing device (HA/CI/bone) for >6 months; and (d) parent can read English, and either speak/understand English or use ASL; and (e) parent lives in a state with an established referral network for parents of DHH children if additional services are needed (e.g. one of the current 39 U.S. states with an authorized chapter of the national Hands & Voices organization). Exclusion criteria: (a) active child protective services case; (b) parent already has accessed behavioral health services for the child; and (c) parent participated in Aim 3.

(2) Up to 200 students will be recruited from the University of Kentucky. Inclusion criteria: (a) current student at the University of Kentucky; (b) native English speaker and (c) age 18 years old or older. Exclusion criteria: (a) ever diagnosed with a hearing loss; (b) more than minimal experience listening to speech produced by deaf or hard of hearing children; and (c) previously participated in this study.

AIM 5 (IMPLEMENTATION)

In Aim 5, we will involve three groups of participants: (1) interventionists ("parent coaches"), (2) key stakeholders, and (3) parents who received the FCU-DHH intervention.

(1) Interventionists ("parent coaches"): In Aim 5, parent coaches (n=10) will be enrolled as study participants. Additional coaches will be enrolled if previously enrolled coaches withdraw from the study. Inclusion criteria: 1) age 18 years or older, and 2) willing to complete the FCU-DHH training curriculum, deliver FCU-DHH, and provide interventionist-level data. Exclusion criteria: none

(2) Key Stakeholders: During Aim 5, we will identify key stakeholders (n=10), including hearing healthcare providers, clinic and state administrators, and representatives of the non-profit organization Hands & Voices or other organizations that support DHH children and/or their families. Inclusion criterion: the participant must be in one of the above categories. Exclusion criteria: None.

(3) Parents: In Aim 5, we will purposively select parents with varying outcomes and characteristics (n=20) who received the FCU-DHH to participate in post-intervention key informant interviews.

Attachments

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Kentucky State Census, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported at Continuation Review time for Pre-2019 FDA-regulated Expedited review and Full review applications):

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:	0	0		
Asian:	7	9		
Black/African American:	20	35		
Latinx:	9	13		
Native Hawaiian/Pacific Islander:	0	0		
White:	145	325		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:	3	4		

If unknown, please explain why:

more than 1 race

Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depending on the subject categories which apply to your research. If the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check populations which the research does not specifically target. For example: a large record review of a diverse population may incidentally include a prisoner or an international citizen, but you should not check those categories if the focus of the study has nothing to do with that status.

Check All That Apply (at least one item must be selected)

- ☑ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☑ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking (translated long or short form)

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults
- Economically or Educationally Disadvantaged Persons

Other Resources:

- UKMC Residents or House Officers [see requirement of GME]

- ☐ International Citizens
- ☑ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☐ Patients
- ☐ Appalachian Population

- Non-English Speaking [see also the E-IRB Research Description section on this same topic]
- International Citizens [DoD SOP may apply]
- Military Personnel and/or DoD Civilian Employees

Assessment of the potential recruitment of subjects with impaired consent capacity (or likelihood):

☐ Check this box if your study does NOT involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

Does this study focus on adult subjects with any conditions that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

○ Yes ◉ No

If Yes and you are not filing for exemption certification, go to "Form T", complete the form, and attach it using the button below.

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

SUBJECT CHILDREN

0 unresolved comment(s)

SECTION 1. Risk Level

Complete this section and include it with your IRB application submission. *In Kentucky, a child is an individual less than 18 years of age unless the individual is legally emancipated.*

Note: the explanation(s) you are being asked to provide in Section 1 correlate(s) to the risk level you selected in the Risk Level section.

Minimal risk means that the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life *of a healthy child* or during the performance of routine physical or psychological exams or tests.

FOR FDA REGULATED RESEARCH: Based on the 2013 FDA final rule Subpart D, a placebo control arm of a clinical trial must be approved under either Risk Category 1, Risk Category 3], or Risk Category 4]. FDA does not consider administration of a placebo to offer a prospect of direct benefit to an individual subject under Subpart D, Risk Category 2 [21 CFR 50.52].

Not involve greater than minimal risk.

In the Risk Level section of the IRB Application you indicated your research does not involve greater than minimal risk.

A. Explain why your research does not involve greater than minimal risk:

Children (ages 2-9 years) in the study may or may not participate in evidence-based parenting sessions delivered to their parents by trained and supervised study interventionists. These sessions focus on basic parenting skills including praise, positive reinforcement, limit-setting, and consistent consequences. Children in both the intervention and control group will participate in annual speech and language evaluations which are similar to those conducted by audiologists and speech and language pathologists, thus similar to assessments they undergo in usual care. The children's confidentiality will be protected using procedures described in the Research Description.

SECTION 2. Assessment and Evaluation of the Risks

For details, refer to the UK IRB's Policy on Children in Research.

A. Provide justification for the participation of children as research subjects in your study.

The purpose of the study is to assess the effects of an adapted evidence-based parenting intervention on parent behaviors, child behaviors, child adherence to wearing their hearing equipment, and child speech/language outcomes. For all four outcomes, participation of the children is needed in assessment of outcomes, including videotaped tasks, parent-report measures, and measures administered directly to children. Children's direct participation in the parenting intervention is not necessary.

B. Has this research been conducted in adults? ◉ Yes ○ No

If yes, is there any indication that the proposed research would benefit, or at least not be harmful to children?

There are 40 years of research evidence demonstrating the benefits of evidence-based parenting interventions to children and families.

C. Indicate how many children you propose to enroll in the study: 147

Note: Whenever possible, involve the fewest number of children necessary to obtain statistically significant data which will contribute to a meaningful analysis relative to the purpose of the study.

Justify this number:

Two children have already participated in Aim 3, the piloting of trial procedures. We plan to enroll 125 parent-child dyads (125 parents, 125 children; 72 dyads randomized to the intervention and 53 dyads randomized to the control condition) in the effectiveness trial, Aim 4. This number was determined by our biostatistician based on the individually-randomized trial design, alpha=.05, the potential of clustering at the interventionist level, and the need to detect a medium-sized effect on the primary outcome (parenting behaviors).

At the time of the 2024 Continuation Review, there were an additional 15 children whose parents enrolled them in the study (i.e., signed the e-consent form) but never completed the baseline assessment. Those children never participated in study activities (i.e., the videotaped parent-child tasks and the child language assessements). Those parent-child dyads were considered withdrawn or lost-to-follow-up and are described in Question 7 of the Continuation Review form. They are included in the Subject Demographics table because we considered them "enrolled" once they signed consent, and in some cases parents began their questionnaires. We have increased our proposed # of enrolled children above by 20 (for the 15 current withdrawn/LTFU and the potential of a few more as we have 2 more parent-child dyads to fully recruit). However, only 127 children will actually have involvement in our study (i.e., the videotaped parent-child tasks and the child language assessements). Once a family completed baseline assessments, they were randomized and considered fully enrolled (i.e., one of our final 125 dyads).

D. Check all that apply:

- [x] My research involves children 6 years of age or older.
- [x] My research involves children under 6 years of age.

Indicate how assent will be solicited by selecting all that apply:

Assent will be solicited from: ○ All Children ◉ Sub-group of children ○ None of the children

I am requesting waiver of the requirement for assent from: ○ All Children ◉ Sub-group of children ○ N/A

Indicate justification for waiving assent for these children: (Check all that apply)

- [ ] 1. The intervention or prospect involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child/children and is available only in the context of the research.
- [x] 2. The children are not capable of providing assent based on the age, maturity, or psychological state.
- [ ] 3. The capability of the children is so limited that they cannot reasonably be consulted
- [ ] 4. Other (explain)

** If you checked question 3, please explain:

** If you checked question 4, please explain:

E. Unless you are requesting a waiver of the requirement for assent for ALL children, you must answer “yes” to at least one of the following two statements.

Note: All assent forms or scripts must be attached to the “Informed Consent" section of this application. Be sure to save your responses in this section first.

For Children 6-11:
Assent will be obtained verbally. I have attached an assent script for obtaining verbal assent for IRB review.

◉ Yes ○ No

For Children 12-17:
The children will document assent by signing an assent form, or provide assent verbally if approved by the IRB, depending on the circumstances outlined in the application. I have attached an assent form or script for IRB review.

○ Yes ◉ No

F. Explain how study personnel will evaluate dissent (e.g., behaviors that would indicate the child does not want to participate such as moving away, certain facial expressions, head movements, etc.). If your study involves only children under 6 years of age, enter “N/A” below.

Children who refuse to participate in the speech/language measures or videotaped tasks will be determined to be dissenting at that assessment time point.

G. Describe how parental permission will be obtained.

Informed consent process using our IRB-approved consent form.

I have attached a parental permission form for IRB review. ◉ Yes ○ No

Parental permission forms must be attached in the “Informed Consent" section of this application. Be sure to save your responses in this section first.

Note that for Risk Category 3 or Risk Category 4 where research involves more than minimal risk without the prospect of direct benefit to the individual child, the permissions of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available OR or only one parent has legal responsibility for the care and custody of the child.)

I am requesting

☐ The permission of both parents unless one parent is deceased, unknown, incompetent, or not reasonably available or when only one parent has legal responsibility for the care and custody of the child. **(required for Risk Category 3 or Category 4 Research).**

☑ The permission of one parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. **(permitted for Risk Category 1 or Category 2 Research).**

☐ Waiver of the requirement for signatures on parental permission forms. (Complete the “Request for Waiver of Signatures” questions in the in the Informed Consent/Assent Process/Waivers Section)

☐ Waiver of the requirement for parental permission.

Note: Parental/guardian permission cannot be waived for FDA regulated studies that are greater than minimal risk (Risk Categories 2-4).

Parental Permission Waiver Options

○ Complete the "Request for Waiver of Informed Consent Process” questions in the Informed Consent/Assent Process/Waivers Section.

○ Justify that the research study is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable request (e.g., abused children):

Justify:

H. Describe how study personnel will ensure that a parent is present when the child participates in any research activities.
Note: If the nature of the research is such that it is not appropriate to have a parent present (e.g., research into sensitive personal issues, physical examinations of teenagers, etc.), explain why.

Videotaped tasks involving children must be completed with the primary parent participant who provided consent, and speech and language assessments will be also be completed with a parent present. Parents are the recipients of the parenting intervention, and the child's presence is not required, so the intervention cannot be delivered without a parent present.

I. Describe the study personnel expertise for dealing with children at the ages included and whether they are knowledgeable and sensitive to the physical and psychological needs of the children and their families. Explain how the facility in which the research will be conducted is appropriate in relation to environment and/or equipment accommodating to children.

Interventionists and data collectors will be trained extensively in the parenting intervention and in the administration of the study's battery of measures, respectively. In addition, the interventionists will be supervised by a licensed clinical social worker specializing in child and family mental health. Data collection and intervention sessions are designed to be conducted in the home or at a private mutually agreed-upon location.

J. If applicable, provide additional information that may support your request to involve children in research.

N/A

SECTION 3. Wards of the State

If you need to activate this section:

- go to the Subject Demographics section;
- select “Wards of State (Children)” in the categories of subjects and controls to be included in your study;
- save that section.

A. 45 CFR 46.409(a)

Please indicate which category describes your research proposal:

- ○ Research is related to subjects’ status as ward of the state.
- ○ Research is conducted in schools, hospitals, or similar setting(s) in which the majority of children involved in the study are NOT wards.

B. 45 CFR 46.409(b)

Federal regulations state that an advocate must be appointed in circumstances where investigators enroll wards of the state for research studies which are greater than minimal risk **specifically risk category 3 or 4**. Please answer the following questions:

a) Will the advocate serve in addition to a guardian or in loco parents?

○ Yes ○ No

b) Check the applicable item:

- ○ Each child will have their own advocate.
- ○ One advocate will serve for all children enrolled in the study.
- ○ N/A

c) Explain why the advocate has the background and experience to serve as an advocate for the study.

d) Federal regulations state that an advocate cannot be associated with the study, investigator or organization. Please provide assurances that the advocate does not meet any of the criteria listed above.

SECTION 4. Children Located Outside the State of Kentucky

Does your study involve children outside the state of Kentucky? ◉ Yes ○ No

Provide information regarding the state definition of legally authorized representative, child, or guardian, as applicable to the research and to the federal definitions. [If the research is to be conducted in more than one state outside of Kentucky, provide this information for each state.]:

We have taken the most conservative definition of a legally authorized guardian for all states: biologic or adoptive custodial parent, or a court-appointed legal guardian. Even though some states may have other exceptions, for simplicity, we will ask the following question(s) for every participant during the consent process: "are you the biologic or adoptive custodial parent of this child?" If no, "are you a court-appointed legal guardian of this child?"

Guidance on Consent and/or Authorization by a Legally Authorized Representative

Consistent with Kentucky health care decision statutes for choosing a legally authorized representative for children, the following responsible parties in the order of priority listed shall be authorized to make research participation decisions on behalf of the child: (a) the judicially-appointed guardian of the person, if the guardian has been appointed and if the decisions to be made under the consent are within the scope of the guardianship; (b) the parent of the child.

Definitions

For definitions of “child/children”, emancipated individuals, “legally authorized representative”, “guardian”, “assent”, and “permission”, see the ORI/IRB Informed Consent Standard Operating Procedures (SOP).

INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

For creating your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and edit to match your research project.

Additional Resources:

- Informed Consent/Assent Website
- Waiver of Consent vs. Waiver of Signatures
- Sample Repository/Registry/Bank Consent Template

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- If another site is serving as the IRB for the project, attach the form as a “Reliance Consent Form” so the document will not receive a UK IRB approval stamp; the reviewing IRB will need to stamp the consent forms.
- Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
- It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.
- Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.
  Document Types that do NOT get an IRB approval stamp are:
  - "Highlighted Changes",
  - "Phone Script", and
  - "Reliance Consent Form",
  - "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must:

   a) provide a response in the text box below describing how investigators will obtain consent/assent, and
   b) check the box for at least one of the consent items and/or check mark one of the waivers

2. If applicable attach each corresponding document(s) **as a read-only PDF**.
3. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

Check All That Apply

- [x] Informed Consent Form (and/or Parental Permission Form and/or translated short form)
- [x] Assent Form
- [x] Cover Letter (for survey/questionnaire research)
- [x] Phone Script
- [x] Informed Consent/HIPAA Combined Form
- [ ] Debriefing and/or Permission to Use Data Form
- [ ] Reliance Consent Form
- [ ] Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- [ ] Stamped Consent Doc(s) Not Needed

Attachments

Attach Type	File Name
Assent Form	Aim 4 child assent (6yr+)_CLEAN 3.16.23.pdf
Survey Consent	Aim 4_Student_BIT scoring consent.pdf
Informed Consent/Parental Permission	Aim4_Additional Caregivers_CLEAN_7.15.22.pdf
Informed Consent/Parental Permission	Aim 5_Parent interviews.pdf
Informed Consent/Parental Permission	Aim 5_Stakeholder interviews_CLEAN 9.18.25.pdf

Informed Consent Process:

Using active voice, in the text box below, describe how investigators will obtain consent/assent. Include:

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)
- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

Will electronic consent form/process be utilized on-site or remotely for this study?

◉ Yes ○ No

If yes, in addition to addressing the above bullet points, describe the e-consent method and platform, including any hyperlinks, videos, or enhancements used to convey information, if applicable. Attach a representation of the e-consent with signature fields. For guidance, see the ORI E-Consent web page.

Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Special considerations may include:

- Obtaining consent/assent for special populations such as children, prisoners, or people with impaired decisional capacity
- *Research Involving Emancipated Individuals*
  If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **prior to submitting this application to the IRB**. Include research legal counsel's recommendations in the "Additional Information" section as a separate document.
- *Research Involving Non-English Speaking Subjects*
  For information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.
- *Research Repositories*
  If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template.

Eligible participants in all study aims who are willing to enroll will each be individually informed in detail about the study goals and procedures, including: why they are being invited to participate; who is conducting the study; what is the study's purpose; exclusion criteria; study location and time requirements; what they will be asked to do; possible risks and discomforts; possible benefits; voluntariness of participation; costs of participation; confidentiality and its limits; rights to end participation early; payment for their time; and contact information for the PI and Office of Research Integrity at the University for questions, suggestions, concerns, or complaints. A copy of the signed informed consent form will be provided to each participant.

AIM 1 (CAB) - COMPLETE

In Aim 1, there are no subjects, so no informed consent process is needed.

AIM 2 (ADAPTATION) - COMPLETE

(1) Parent/Caregiver and Key Stakeholders: In Aim 2, Dr. Studts or research staff trained in human subjects protection will conduct the process of informed consent with each parent/caregiver and key stakeholder participant prior to initiating study procedures. Written informed consent will be required from all parent/caregiver and key stakeholder participants in Aim 2.

AIM 3 (PILOT) - COMPLETE

(1) Parents/Caregivers and Children: In Aim 3, research staff trained in human subjects protection will conduct the process of informed consent with each parent/caregiver participant prior to initiating study procedures. The parents/caregivers will provide written informed consent for themselves and on behalf of the child participants, who are too young (ages 2-5) to be able to provide assent or consent. The trained research staff member will contact the potential participant by phone to review eligibility and all required elements of informed consent. We believe that by allowing UK research staff, and not the parent coaches (who will also be trained in human subjects protection), we will decrease any risk of coercion in the event of a pre-existing relationship among parents of DHH children, and additionally, the UK research staff will be more familiar with the study as a whole and, therefore, better able to answer questions and ensure complete understanding of the study and associated expectations. Upon the participant's verbal consent, the UK research team will mail a packet of documents to include: 1) a cover letter with detailed instructions, 2) a copy of the informed consent document to be signed, and 3) baseline data assessment forms to be completed by the participant at his or her convenience. The research staff will obtain the signed informed consent document at the first face-to-face meeting with the participant at which the research staff member will conduct additional assessments with the parent and the child. Research staff will

arrive at that appointment with additional copies of the informed consent document in the event that the participant misplaced the document. No assessment forms or other research material will be collected from the participant until the signed informed consent document is obtained. The signed consent document will be separated from the data forms when filed in the research office.

Additional caregivers who wish to participate in Aim 3 FCU-DHH sessions will complete the process of informed consent with the parent coach (trained in human subjects protection) who will deliver those sessions. The rationale for this procedure is that study staff may not know about additional caregivers' availability or intentions to attend sessions until they actually show up at the appointment. Additional caregivers will not complete any baseline or follow-up measures, nor will they receive any incentives to participate. Additional caregivers who participate in FCU-DHH sessions will also receive a copy of their signed informed consent documents.

(2) Interventionists ("parent coaches"): To ensure their willingness to participate in the study prior to the FCU-DHH training, Dr. Studts will call each parent coach in Aim 3 to thoroughly explain the study. Written informed consent documents will be obtained prior to any data collection or training and will be stored separately from any data forms.

AIM 4 (EFFECTIVENESS)

(1) Parents/Caregivers and Children: In Aim 4, research staff trained in human subjects protection will conduct the process of informed consent with each parent/caregiver participant prior to initiating study procedures. The parents/caregivers will provide written informed consent for themselves and on behalf of the child participants who are ages 3-6 during enrollment. A trained research staff member will review eligibility and all required elements of informed consent timepoint during the recruitment phone call, assuring that all of the parent's questions are answered. When the parent expresses interest in the study, the informed consent document will be sent either via email (using the E-Consent Framework in REDCap – see REDCap screenshots) or with a paper copy by mail if requested. Parents will be provided with phone and email contact information for the research team if they have any additional questions when reviewing the informed consent document. If consent is documented via the online REDCap instrument, a PDF of the signed version will be automatically emailed to the participant. If the consent form is mailed, an additional paper copy will be provided to the participant, along with a stamped envelope to return the signed copy. Receipt of any signed informed consent documents received by mail will be documented in REDCap. No assessment forms or other research material will be collected from the participant until the signed informed consent document is obtained. The signed paper consent documents will be separated from the data forms when filed in the research office. Electronic copies will be stored in REDCap.

Active study participants who signed informed consent prior to the July 2022 IRB modification that changed to all remote data collection procedures (vs. the previous protocol for conducting in-person language assessments with children at 12-, 24-, and 36-mo assessments), will be re-consented and will sign the updated IRB-approved consent form. Trained research staff members will contact each of these participants (n=32), explain the changes, review all required elements of informed consent, and send the informed consent document using the same methods above (i.e., either an emailed link via REDCap, or by mail if preferred by the participant). Signed copies of both the original and the updated consent forms will be kept on file for these participants. New participants will sign the updated consent form.

At any point in the study when a child is 6 years or older, verbal assent will be obtained using the provided script. The assent process may be done remotely (i.e., by videoconference when the videotaped tasks are recorded by research staff remotely), and the child's assent will be documented by research staff via a Data Collection Checklist, including the method of assent (e.g., a nod, a "yes", or beginning the research tasks) and who was present during the process. Documentation of assent (date, method, who present, name of authorized person obtaining informed assent) will be entered into and stored in REDCap.

Additional caregivers who wish to participate in any Aim 4 data collection (e.g., videotaped tasks) or FCU-DHH sessions will complete the process of informed consent with either the research staff or the parent coach, depending on the type of session the additional caregiver first attends. Parent coaches will receive CIRTification human subjects protection training and will specifically be trained in the consent process for additional caregivers. The additional caregiver consent form will be programmed into a separate REDCap project from the main REDCap project used for recruitment, consent, and data collection for the primary parent and child. The E-Consent Framework will allow that consent document to be delivered as an online survey, similar to the description above for the primary participant. However, for the additional caregiver, the REDCap survey will be set as a "public link." This will allow parent coaches (who will not be granted access as "users" on any REDCap project) to deliver the consent document as needed (e.g., if an additional caregiver decides to attend an FCU-DHH session). The rationale for this procedure is that research staff may not know about additional caregivers' availability or intentions to attend sessions until they actually show up at the appointment. Additional caregivers will not complete any paper-based baseline or follow-up measures, nor will they receive any incentives to participate. Additional caregivers will also receive a copy of their signed informed consent documents.

Informed consent (and, for children ages 6 and older, assent) will be reviewed at the initiation of each subsequent assessment session, scheduled to occur once every 6 months for 3.25 years.

(2) Students scoring BIT speech intelligibility instrument: research staff trained in human subjects protection will conduct the process of informed consent, reviewing eligibility criteria and all required elements of informed consent, assuring that all of the student's questions are answered. A waiver of signatures for informed consent is requested due to the minimal risk.

AIM 5 (IMPLEMENTATION)

(1) Interventionists ("parent coaches"): In Aim 5, Dr. Studts or Ms. Jacobs will complete the informed consent process with each interventionist, either in person or by phone, before their training in the FCU-DHH and completion of baseline interventionist assessment measures is initiated. Written informed consent (either by the online REDCap e-consent module, or by paper copy prior to training) will be required from all interventionists. Interventionists who were trained before the study paused for COVID-19

shutdowns will be re-consented when the study relaunches with updated study procedures.

(2) Key Stakeholders: In Aim 5, Dr. Studts or other research staff trained in human subjects protection will conduct the process of informed consent with each key stakeholder participant prior to initiating study procedures. Written informed consent (either by the online REDCap e-consent module, or by paper copy at the time of the interview) will be required from all key stakeholder participants.

(3) In Aim 5, parents (n=20) from the intervention group will be invited to participate in key informant interviews. Research staff will conduct a process of informed consent that is separate from their participation in Aim 4. Written informed consent (by the online REDCap e-consent module) will be required from all key stakeholder participants.

If participants have questions, requests, suggestions, concerns, or complaints about the study, they will be encouraged to contact the PI. If participants have questions about their rights as a volunteer in this research, they will be encouraged to contact the Office of Research Integrity at the University of Kentucky. In both cases, participants will be assured of and provided with a safe, confidential, and reliable means of discussing problems, questions, and/or concerns.

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, complete, Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting a waiver of the requirement for the informed consent process.

☐ I am requesting an alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered and/or omitted, and justify the alteration.

SECTION 2.

Explain how each condition applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

☑ Request for Waiver of Signatures

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (e.g., a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk to the subject, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study.

*If the IRB approves a waiver of signatures, participants must still be provided oral or written information about the study. To ensure you include required elements in your consent document, use the **Cover Letter Template** as a guide. There is an English and a Spanish version.*

○ **Option 1**

Describe how your study meets these criteria:

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

◉ **Option 2**

Describe how your study meets these criteria:

a) The research presents no more than minimal risk to the participant:

Student participants are not providing any personal data in the research task; they will be transcribing the words they hear spoken by a child participating in our study. Student names and emails will not be linked to their responses.

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

The informed consent process will involve a written statement preceding the scoring task, as is typically used in survey research. The statement will describe in detail the research, its purpose, the expected duration of participation, and the procedures. A HSP-trained member of our study personnel will review the consent document with all potential participants and answer any questions. Students who agree to participate will be allowed to begin the research task.

○ **Option 3**

Describe how your study meets these criteria:

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

STUDY PERSONNEL **0 unresolved comment(s)**

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must click the 'Save Study Personnel Information' button.

◉ Yes ○ No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is required for a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed below. ***Residents and students who are PI's are encouraged to designate the faculty advisor or at least one other individual as a contact with an editor role (DP).***
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR/FR, MR) or 'Other Review", and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature:

- Search for personnel;
- Click "select" by the listing for the person you want to add;
- For each person, specify responsibility in the project, whether authorized to obtain informed consent, AND denote who should receive E-IRB notifications (contact status).

NOTE: Study personnel must complete human subject protection (HSP) and Responsible Conduct of Research (RCR) training before implementing any research procedures. For information about training requirements for study personnel, visit UK's HSP FAQ page, the RCR Home page, or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (HSPTrainingSupport@uky.edu) for credit.

Study personnel assisting in research project:

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Ashworth French	Melinda	Data Collection	SP	Y	N		P	Y	09/07/2024	Y	N	11/05/2019	N	N
Baker	Gine	Project Assistance/Support	SP	Y	N		P	Y	03/03/3000		N	11/04/2019	N	Y
Bellnier	Laura	Recruitment	DP	Y	N		P	Y	07/01/2025	Y	N	10/25/2022	N	Y
Bush	Matthew	Co-Investigator	SP	Y	N	MD, PhD	P	Y	04/10/2023	Y	N	08/22/2018	N	Y
Cranford	William	Data Analysis/Processing	SP	N	N		P	Y	07/29/2024	Y	N	06/04/2024	N	N
Creel	Liza	Co-Investigator	SP	N	N	PhD, MPH	N	Y	03/03/3000		N	07/26/2018	N	Y
Elliot	Brenda	Project Assistance/Support	SP	Y	N		N	Y	03/03/3000		N	03/29/2023	N	Y
Faulkner	Courtney	Project Assistance/Support	SP	Y	N		P	Y	12/18/2024	Y	N	12/18/2024	N	Y
Fields	Madilyn	Project Assistance/Support	SP	N	N		P	Y	08/26/2025	Y	N	10/25/2022	N	Y
Fromholt	Kathryn	Project Assistance/Support	SP	N	N		P	Y	03/03/3000		N	11/04/2019	N	Y
Hails	Katherine	Data Analysis/Processing	SP	N	N		N	Y	03/03/3000		N	03/18/2025	N	Y
Hoaglin	Turi	Project Assistance/Support	SP	Y	N		N	Y	03/03/3000		N	03/29/2023	N	Y
Karnik	Kelsey	Data Analysis/Processing	SP	N	N		P	Y	07/19/2023	Y	N	01/08/2025	N	Y
Lowman	Julie	Co-Investigator	SP	Y	N	PhD	P	Y	03/18/2024	Y	N	08/22/2018	N	Y
Mahairas	Anthony	Data Collection	DP	Y	N		P	Y	09/11/2024	Y	N	09/13/2021	N	Y
McWhirter	Anna	Data Analysis/Processing	SP	N	N	PhD	N	Y	03/03/3000		N	02/07/2025	N	Y
Montgomery	Brooke	Project Assistance/Support	SP	Y	N		P	Y	03/03/3000		N	11/04/2019	N	Y
Ormond	Persis	Project Assistance/Support	SP	N	N		P	Y	04/28/2025	Y	N	05/02/2025	N	Y
Reiter	Lisa	Data Analysis/Processing	SP	N	N	PhD	N	Y	03/03/3000		N	02/07/2025	N	Y
Roof	Sarah	Project Assistance/Support	SP	N	N		N	Y	03/03/3000		N	04/28/2020	N	Y
Schuhmann	Laura	Data Collection	SP	Y	N		P	Y	09/26/2022	Y	N	11/05/2019	N	N
Streevel	Sarah	Project Assistance/Support	SP	Y	N		P	Y	03/03/3000		N	11/04/2019	N	Y
Studts	Christina	Co-Investigator	DP	N	N	PhD	P	Y	03/03/3000		N	03/16/2023	N	Y

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Travis	Lori	Consultant/Advisor	SP	N	N		N	Y	03/03/3000		N	11/10/2019	N	Y
Urban	Teri	Project Assistance/Support	SP	Y	N		N	Y	03/03/3000		N	03/29/2023	N	Y
Westgate	Philip	Data Analysis/Processing	SP	N	N		P	Y	05/25/2023	Y	N	06/04/2024	N	Y
Willson	Jennie	Data Collection	SP	Y	N		P	Y	09/23/2022	Y	N	11/05/2019	N	N
Agro	Liz	Project Assistance/Support	SP	Y	N		P	Y	03/03/3000		Y	09/13/2021	N	Y
Antel	Mallory	Project Assistance/Support	DP	Y	N		P	N	07/22/2019	Y	Y	03/06/2020	N	N
Barber	Kristan	Project Assistance/Support	SP	Y	N		N	Y	03/03/3000		Y	02/21/2025	N	Y
Bernard	Jate	Project Assistance/Support	SP	Y	N		S	Y	02/19/2025	Y	Y	04/29/2025	N	Y
Board	Ryleigh	Project Assistance/Support	SP	N	N		P	N	06/09/2022	Y	Y	12/18/2023	N	N
Board	Ryleigh	Project Assistance/Support	SP	N	N		N	Y	03/03/3000		Y	07/15/2022	N	Y
Cornell	Cady	Project Assistance/Support	DP	Y	N		P	N	08/28/2017		Y	03/06/2020	N	N
Davis	Amanda	Project Assistance/Support	SP	N	N		P	N	07/29/2022	Y	Y	12/18/2023	N	N
Dyer	Kris	Project Assistance/Support	SP	Y	N		P	Y	06/10/2024	Y	Y	09/09/2019	N	Y
Goble	Emily	Recruitment	DP	Y	N		P	N	01/24/2018		Y	01/04/2021	N	N
Grider	Kristi	Data Collection	SP	Y	N		P	Y	03/03/3000	Y	Y	10/25/2022	N	N
Hall	Rebekah	Data Collection	SP	Y	N		P	N	10/10/2019		Y	03/06/2020	N	N
Haney	Michelle	Project Assistance/Support	SP	Y	N		P	Y	03/03/3000		Y	10/25/2022	N	Y
Hatfield	Miranda	Project Assistance/Support	SP	N	N		P	Y	08/27/2025	Y	Y	01/04/2021	N	Y
Jaramillo	Jessica	Consultant/Advisor	SP	N	N		P	N	11/02/2019		Y	12/21/2021	N	N
Lester	Catharine	Co-Investigator	SP	Y	N	MSSW	N	Y	03/03/3000		Y	11/10/2019	N	Y
Loheide	Sarah	Project Assistance/Support	SP	N	N		P	N	08/31/2018		Y	01/04/2021	N	N
Madabhushi	Vashisht	Project Assistance/Support	SP	N	N		P	N	05/04/2022	Y	Y	03/06/2020	N	N
Moraska	Callihan	Project Assistance/Support	DP	Y	N		P	N	08/24/2020		Y	01/04/2023	N	N
Mullikin	Grace	Project Assistance/Support	SP	Y	N		P	N	01/20/2022	Y	Y	12/18/2023	N	N
Muncy	Tonya	Data Collection	SP	Y	N		P	N	10/08/2019		Y	09/13/2021	N	N
Patton	Kristin	Project Assistance/Support	SP	Y	N		P	Y	03/03/3000		Y	09/13/2021	N	Y
Qureshi	Sadia	Data Collection	SP	Y	N		P	N	10/10/2019		Y	09/13/2021	N	N
Rojas Ramirez	Marcia	Project Assistance/Support	DP	Y	N		P	Y	04/15/2024	Y	Y	09/09/2019	N	Y
Roof	Sarah	Project Assistance/Support	SP	Y	N		P	N	10/22/2019		Y	04/28/2020	N	N
Schuh	Marissa	Project Assistance/Support	SP	Y	N		P	Y	04/17/2025	Y	Y	01/04/2023	N	N
Speaks	Hannah	Data Analysis/Processing	SP	N	N		P	Y	01/02/2025	Y	Y	12/18/2023	N	Y

RESEARCH DESCRIPTION

0 unresolved comment(s)

You may attach a sponsor's protocol pages in the "Additional Information" section and refer to them where necessary in the Research Description. However, each prompt that applies to your study should contain at least a summary paragraph.

Pro Tips:

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section or under the Additional Information section to include supplemental information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background

Include a brief review of existing literature in the area of your research. You should identify gaps in knowledge that should be addressed and explain how your research will address those gaps or contribute to existing knowledge in this area. For interventional research, search PubMed and ClinicalTrials.gov for duplicative ongoing and completed trials with same condition and intervention(s).

Deaf and hard of hearing (DHH) children are at increased risk for disruptive behavior problems, but are less likely than peers with typical-hearing to receive behavioral interventions. The public health burden posed by behavioral problems in DHH children is significant: As the most common neonatal sensory disorder in the United States, infant hearing loss occurs in 1.6 per 1000 births. Early intervention for hearing impairment is the primary treatment goal for DHH children and focuses on restoration of hearing, language development, and facilitation of parent-child communication. Although early diagnosis and treatment of hearing loss and speech improve language development, improvements in behavior often do not result from these interventions alone. Even after standard of care hearing and speech interventions, DHH children are twice as likely to exhibit behavioral problems as their typical hearing peers, with up to 50% experiencing significant disruptive behavior problems.

Untreated early childhood behavioral problems frequently persist through adulthood, with a trajectory of costly negative outcomes including school failure, substance abuse, criminal justice involvement, and poor health-related quality of life. These outcomes represent a nearly ten-fold increase in costs associated with education, health, and criminal justice through early adulthood. Behavioral parent training (BPT) interventions have consistently demonstrated efficacy and effectiveness in reducing disruptive behavior problems and their costly consequences in children with typical hearing, especially when delivered in early childhood. There is a significant gap, however, in the delivery of behavioral interventions to parents of DHH children. In response to this need, our team recently piloted an existing evidence-based BPT intervention—the Family Check-Up—with parents of preschool-aged DHH children. Results of the trial revealed limitations of "off-the-shelf" interventions with this population, as well as barriers to widespread implementation in the field. Thus, we plan to systematically adapt the Family Check-Up (FCU) to make it responsive to the needs and preferences of parents of DHH children, then test the effectiveness of the adapted intervention (FCU-DHH) in a type 1 hybrid effectiveness-implementation trial.

Objectives

List your research objectives. Please include a summary of intended research objectives in the box below.

AIM 1 (CAB) - COMPLETE: To convene a Community Advisory Board (CAB) comprising parents of DHH children, hearing healthcare providers, and staff from the Kentucky Office for Children with Special Health Care Needs (OCSHCN).
AIM 2 (ADAPTATION) - COMPLETE: To systematically adapt the evidence-based Family Check-Up (FCU) BPT by incorporating the preferences and perspectives of our CAB; experts in child hearing loss, language development, and BPT interventions; and parents and providers who engage in key informant interviews and focus groups.
AIM 3 (PILOT) - COMPLETE: To pilot the adapted Family Check-Up (FCU-DHH) with two families, appraising details of the protocols for our R01 hybrid effectiveness-implementation trial.
AIM 4 (EFFECTIVENESS TRIAL): Using a randomized controlled trial (RCT) design, to test 4 hypotheses regarding the effects of the FCU-DHH on the target population. Compared to parents of young DHH children assigned to treatment-as-usual (TAU), parent-child dyads assigned to FCU-DHH will demonstrate:
Hypothesis 1: Increased use of positive parenting strategies (primary outcome)
Hypothesis 2: Lower levels of child disruptive behavior problems
Hypothesis 3: Increased adherence to wearing hearing rehabilitation devices as prescribed
Hypothesis 4: Improved language development outcomes over time
AIM 5 (IMPLEMENTATION): Based on the Consolidated Framework of Implementation Research, to identify factors within the domains of outer setting, intervention characteristics, and interventionist characteristics influencing the implementation of the intervention, as well as preliminary implementation outcomes (i.e. acceptability, adoption, recruitment/retention, fidelity, and costs).

Study Design

Describe and explain the study design (e.g., observational, secondary analysis, single/double blind, parallel, crossover, deception, etc.).

- *Clinical Research*: Indicate whether subjects will be randomized and whether subjects will receive any placebo.
- *Community-Based Participatory Research*: If you are conducting community-based participatory research (CBPR), describe

strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.
- *Qualitative research*: Indicate ranges where flexibility is needed, if a fixed interview transcript is not available, describe interview topics including the most sensitive potential questions.
- *Research Repositories*: If the purpose of this submission is to establish a Research Repository (bank, registry) and the material you plan to collect is already available from a commercial supplier, clinical lab, or established IRB approved research repository, provide scientific justification for establishing an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance or the UK Research Registry Guidance.

We will (1) employ qualitative methods to elucidate parents' and providers' perspectives and preferences regarding BPT delivery in OCSHCN clinics; (2) incorporate these findings, along with topical expert feedback, into the adaptation of the delivery model of an evidence-based BPT; (3) pilot its delivery by trained interventionists, or "parent coaches;" (4) conduct a RCT of the adapted BPT with parents of young children who are deaf and hard of hearing and who use hearing devices - hearing aids, cochlear implants, and/or bone conduction devices (HA/CI/bone). This trial is a type 1 hybrid effectiveness-implementation trial – it focuses on parent- and child-level outcomes, but also collects data regarding implementation outcomes and factors influencing implementation.

Attachments

Subject Recruitment Methods & Advertising

Describe how the study team will identify and recruit subjects. Please consider the following items and provide additional information as needed so that the IRB can follow each step of the recruitment process.

- How will the study team identify potential participants?
- Who will first contact the potential subjects, and how?
- Will you use advertisements? If so, how will you distribute those?
- How and where will the research team meet with potential participants?
- If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations.
- How you will minimize undue influence in recruitment?
- Attach copies of all recruiting and advertising materials (emails, verbal scripts, flyers, posts, messages, etc.).

For additional information on recruiting and advertising:

- IRB Application Instructions - Advertisements
- PI Guide to Identification and Recruitment of Human Subjects for Research

AIM 1 (CAB) - COMPLETE

In Aim 1, there is no subject recruitment.

AIM 2 (ADAPTATION) - COMPLETE

(1) Parent/caregivers: In Aim 2, potential participants will be identified by co-investigator Ms. Lester using OCHSCN records (approval has been given by the Cabinet for Family and Health Services, which has designated UK's IRB as the IRB of record). Potential participants will also be recruited by means of a flyer that will be posted at OCHSCN and other hearing healthcare practices. The flyers will also be distributed through CAB members to potentially eligible parents, including distribution to parents of Dr. Bush's patients during routine clinic visits at UK Otolaryngology. These participants will be recruited using purposive sampling procedures to ensure representation of several different types of parents, with at least 2-3 participants representing each of the following key parameters: annual household income level (< $20k vs. > $20k), education level (less than high school vs. more than high school), parent age (under age 25 vs. over age 25), parental concern about the child's behaviors (concerned vs. not concerned), degree of child's hearing impairment (mild vs. moderate vs. profound), and type of amplification (hearing aid vs. cochlear implant). No payment, compensation, or incentives will be provided for referring potential participants.

(2) Key stakeholders: In Aim 2, the study investigators will invite hearing healthcare providers, speech and language therapists, and DHH educators through our professional networks throughout the state. Key stakeholder participants may refer additional participants, but no payment, compensation, or incentives will be provided for referring potential participants.

AIM 3 (PILOT) - COMPLETE

(1) Parents/Caregivers and Children: In Aim 3, staff of the OCSHCN will identify families with 2-5 year old children who have hearing loss and have utilized OCSHCN clinic services. OCSHCN will provide the name and contact information of the parent or legal guardian to members of the UK research team trained in human subjects protection (see Memorandum of Understanding between OCSHCN and UK). No payment, compensation, or incentives will be provided for referring potential participants. UK research staff will contact all potential participants and conduct the informed consent process (see Section 6 for more details). If more than one parent/caregiver per family is willing and able to participate in the study (e.g., another parent, grandparent, stepparent), then we will enroll additional caregivers and allow them to participate in the Family Check-Up intervention, but data collection will be restricted to the parent/caregiver participant who was initially recruited.

(2) Interventionists ("parent coaches"): In Aim 3, representatives of the Kentucky Chapter of the Hands & Voices organization will serve as parent coaches. Hands & Voices has agreed as an organization to partner with us on this study and to allow interested

representatives to be trained as interventionists. Dr. Studts will contact all potential participants, describe the study procedures in detail, and ask them if they are interested in voluntary participation as a pilot subject (for research measures) as well as paid employment (for training and delivery of FCU-DHH). Dr. Studts will conduct the informed consent process (see Section 6 for more details).

AIM 4 (EFFECTIVENESS)

(1) Parents/Caregivers and Children: In Aim 4, parent-child dyads (n = 125 dyads/250 individuals) will be recruited. CCTS-developed flyers (including a link and QR code for an informational website hosted by UK's Department of Otolaryngology) will be posted at hearing healthcare clinics across the state, on social media, and on Research Match by the CCTS (see Advertising attachment). Additionally, CCTS-developed brochures will be distributed by hearing health care clinics, by organizations that support DHH children and their families in the United States, and by our CAB. Interested parents will contact our trained research staff using a designated phone number or email address; a link and QR code for a brief REDCap survey will also allow parents to submit their contact information (e.g., name, phone, email, preferences for how we contact them, state of residence), to be called or emailed by our staff. A recruitment video will also be distributed (see Advertising section).

A list of states with established referral networks for DHH parents (as described in the eligibility criteria in Subject Demographics) will be developed in collaboration with our partner Ms. Sarah Roof of Kentucky Hands & Voices. Recruitment efforts will be targeted to those states. Any interested parent who contacts us from a state that is not listed will be told that they are not currently eligible for our study, and they will be provided with national-level resources if they are seeking more services. If a state develops a referral network during the remaining years of our study, we will recontact those previously ineligible parents with their permission.

Additionally, for the UK Ear, Nose, and Throat clinic where Ms. Jacobs (co-investigator and UK site PI) is a senior research project manager and Dr. Bush (co-investigator) is a practicing physician, potentially eligible families will be identified by clinic staff, and contact information will be assembled by research staff via the EPIC medical record system (see HIPAA Waiver of Authorization) and stored securely in REDCap. [Note: no medical information will be extracted from EPIC until the parent/guardian has provided written informed consent (which includes authorization to use or disclose the child's health information) and that family has also completed all baseline research activities.] First, a recruitment letter (see Advertising attachment) will be signed by the patient's audiologist and mailed to potentially eligible families, along with an IRB-approved flyer or brochure. Next, study staff trained in human subjects protection will attempt to call (or text/email if available) families (see Phone Script). Dr. Bush will not conduct any recruiting calls/emails to reduce potential coercion; audiologists will not be considered study personnel, as they will only be introducing the study to their existing patients' families.

For OCSHCN practices, Ms. Travis (co-investigator) will facilitate the development and secure transfer of lists of eligible patients for each clinic using OCSHCN data (approval has been given by the Cabinet for Family and Health Services, which has designated UK's IRB as the IRB of record). Study staff will mail recruitment letters (see Advertising attachment) to eligible families from the OCSHCN clinics introducing them to the study and will call (or text/email if available) families to follow up after letters have been mailed (see Phone Script). Interested parents will contact our trained research staff using a designated phone number.

At the University of Louisville (where Dr. Creel is a co-investigator), clinical staff will provide CCTS-developed study materials to potentially eligible families. For parents who give their permission to share their contact information with the UK study team, the UofL staff member will use a secure REDCap link to provide the UK recruiting team with: parent and child names; phone, email and/or mailing address; child's date of birth or approximate age.

Until recruitment of 125 dyads is complete, potentially eligible families who were either unable to be contacted or who were uninterested at the time of contact will be recontacted by mail with a "we're still recruiting" flyer (see Advertising attachment) and copy of the CCTS-developed study brochure, after a minimum of 9 months has passed since the last contact attempt. The flyer will contain a QR code and URL linked to a brief REDCap survey asking parents to indicate their desire to be recontacted by phone/text by providing: 1) name, 2) preferred phone number, and 3) preference for a phone call or a text for the first contact attempt. Recruitment records will be consulted, and families will be excluded from mailings if they are now ineligible (e.g., child is too old) or if they previously stated that they do not wish to be recontacted. Families who had previously expressed interest in the study but did not complete baseline data collection will also receive a phone call or text to determine if their interest has changed (e.g., the family feels less busy now) since the last contact at least 9 months ago.

All potential parent/caregiver and child participants will be screened for eligibility by trained research staff (on the UK study team) and invited to learn more about the study, including all elements of informed consent. We will use these approaches to minimize any perceived stigmatization or coercion associated with recruitment by healthcare providers, as well as to minimize selection bias in enrollment.

(2) Students scoring BIT speech intelligibility instrument: Co-investigators Ms. Jacobs and Dr. Lowman will identify UK professors who are willing to distribute IRB-approved recruitment flyers, as well as campus locations where they can obtain appropriate permissions to post the flyer. The flyer will contain a URL and QR code for a REDCap page which will: a) review the purpose of the research study and how the speech intelligibility instrument contributes to study aims, b) ask eligibility screening questions; and (c) provide a link for eligible students (according to their responses to the screening questions) to sign up for a date/time to complete the scoring task. To minimize undue influence in recruitment, the study will not be promoted in any course taught by any member of our Study Personnel.

AIM 5 (IMPLEMENTATION)

(1) Interventionists ("parent coaches"): In Aim 5 representatives of the Kentucky Chapter of the Hands & Voices organization will serve as parent coaches. Hands & Voices has agreed as an organization to partner with us on this study and to allow interested

representatives to be trained as interventionists. Dr. Studts, the study's PI who moved from UK to the University of Colorado Denver, or Ms. Jacobs, the UK site PI, will contact all potential participants, describe the study procedures in detail, and ask them if they are interested in voluntary participation as a research subject (for research measures) as well as paid employment (for training and delivery of FCU-DHH). Dr. Studts or Ms. Jacobs will conduct the informed consent process (see Section 6 for more details).

(2) Key Stakeholders: Also in Aim 5, hearing healthcare providers/administrators from participating practices, clinic and OCSHCN and other state administrators, and representatives of organizations that support DHH children and/or their families will be invited by Dr. Studts or Ms. Jacobs to take part in key informant interviews. Dr. Studts or trained research staff will contact all potential participants, describe the study procedures in detail, and ask them if they are interested in voluntary participation as a research subject. Dr. Studts or trained research staff will also conduct the informed consent process (see Section 6 for more details).

(3) Parents: In Aim 5, parents who received the FCU-DHH will be invited by a member of the research team to participate in post-intervention key informant interviews. The research team member will describe the study procedures in detail, ask them if they are interested in voluntary participation as a research subject in this portion of the study, and conduct an informed consent process specific to this interview (see Section 6 for more details).
In Aim 2, potential participants were identified by co-investigator Ms. Lester using CCHSCN records (approved by the Cabinet for Family and Health Services, which has designated UK's IRB as the IRB of record on our past projects). Potential participants were also recruited by means of a flyer that was posted at CCHSCN and other hearing healthcare institutions. The flyers were also distributed through CAB members to potentially eligible parents, including distribution to parents of Dr. Bush's patients during routine clinic visits at UK Otolaryngology. These participants were recruited using purposive sampling procedures to ensure representation of several different types of parents, with at least 2-3 participants representing each of the following key parameters: annual household income level (< $20k vs. > $20k), education level (less than high school vs. more than high school), parent age (under age 25 vs. over age 25), parental concern about the child's behaviors (concerned vs. not concerned), degree of child's hearing impairment (mild vs. moderate vs. profound), and type of amplification (hearing aid vs. cochlear implant). No payment, compensation, or incentives was provided for referring potential participants.

In Aim 4, CCTS-developed flyers and/or brochures (including a link and QR code for an informational website hosted by the UK Department of Otolaryngology) will be posted and distributed at hearing healthcare clinics, through social media, on Research Match by the CCTS, and through our CAB members' network. Additionally, for the OCSHCN clinics a recruitment letter and flyer/brochure will be mailed to potentially eligible families, and for the UK Ear, Nose, and Throat clinic where Dr. Bush (co-investigator) is a practicing physician, a recruitment letter and flyer/brochure will be mailed by his staff to potentially eligible families. At the University of Louisiville (where Dr. Creel is a co-investigator), CCTS-developed flyers and/or brochures will also be posted and distributed.

To assist in answering questions for potential participants, a recruitment video (see attached script) will be distributed through Kentucky Hands & Voices, with a link to the video also placed on the UK ENT informational website. This "Q&A" style video will feature Sarah Roof (Executive Director of Kentucky Hands & Voices, who supervises parent coaches on this project) asking questions about the study to Dr. Tina Studts, the study's PI.

Attachments

Attach Type	File Name
Advertising	Recording transcript submitted to IRB.docx
Advertising	Recruit ltr OCSHCN_relaunch.docx
Advertising	CHAMPS DHH Facebook Post STAMPED.pdf
Advertising	PUBHLTH-033a_flyer PR edit STAMPED.pdf
Advertising	IRB flyer explanation.pdf
Advertising	Recruit ltr UK ENT_clean 12.22.21.docx
Advertising	Recruit ltr UK ENT_tracked changes 12.22.21.docx
Advertising	PUBHLTH-033c_flyer-UK&UofL_STAMPED.pdf
Advertising	PUBHLTH-033_brochure-STAMPED.pdf
Advertising	recontact flyer.pdf
Advertising	Website Content_tracked changes 3.2.23.docx
Advertising	Facebook ad_MARKED March 2023.docx
Advertising	Website Content_clean 3.2.23.docx
Advertising	Facebook ad_CLEAN March 2023.docx
Advertising	CHAMPSDHH one page flyer_July 2023 (3)-STAMPED.pdf
Advertising	CHAMPS ad-STAMPED.pdf
Advertising	CHAMPS recruit flyer_students-STAMPED.pdf

Research Procedures

Describe how the research will be conducted.

- What experience will study participants have?
- What will study participants be expected to do?
- How long will the study last?
- Outline the schedule and timing of study procedures.
- Provide visit-by-visit listing of all procedures that will take place.
- Identify all procedures that will be carried out with each group of participants.
- Describe deception and debrief procedures if deception is involved.

Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project. List medications that are explicitly forbidden or permitted during study participation.

AIM 1 (CAB) - COMPLETE

No research procedures are planned for Aim 1, because our Community Advisory Board members will be collaborators rather than participants (i.e., we are not collecting data from them).

AIM 2 (ADAPTATION) - COMPLETE

(1) Procedures for Parent/Caregiver Participants: During Aim 2, 20 parent/caregiver key informants will provide perspectives on behavioral issues in young DHH children and preferences for intervention content and delivery. A trained RA will conduct digitally audio-recorded key informant interviews (with participant consent) using a semi-structured interview guide addressing perceptions of behavioral problems in young DHH children, perceived availability and effectiveness of parenting interventions for parents of DHH children, preferences regarding content of such an intervention, and perceptions of hearing healthcare as the setting for such an intervention. Initial questions will be open-ended, and follow-up probes will be used to prompt clarification and elaboration of answers. Interviewers also will take field notes during and after each interview. These notes will focus on the tenor of the discussion and the participants' non-verbal presentation. Parents/caregivers will also complete a background questionnaire used in our previous studies to provide sociodemographic data to facilitate description of the sample in analyses (see Form M).

(2) Procedures for Key Stakeholders: In Aim 2, five focus groups will be conducted. Focus groups will be led by Dr. Studts using interview guides tailored for each provider group (see Form M). These will include initial broad questions (e.g., perceptions of child behavior problems in young DHH children), followed by more specific queries as the focus group progresses (e.g., facilitators and barriers to providing behavioral services in hearing healthcare for this target population).

Aim 2 data analyses: All digital recordings of key informant interviews and focus groups will be transcribed. Identifying information will be removed from all transcripts. Qualitative data analyses will be led by Dr. Studts. Facilitated by use of AtlasTi software, transcripts will be coded line-by-line. The investigative team will meet to develop the preliminary codebooks through discussion and refinement. Multiple qualitatively trained graduate students and investigators will establish consensus on codes and coding by reviewing all transcripts in pairs and in larger groups. The investigative team will meet regularly to review the results of the topical coding process and develop a summative grid of themes emerging from the interviews, highlighting preferences for content and delivery of an adapted evidence-based BPT targeting parents of young DHH children. We have used these qualitative methods successfully in prior projects. The information learned in Aim 2 will guide the adaptation of the Family Check-Up intervention to be acceptable and relevant to parents of DHH children.

AIM 3 (PILOT) - COMPLETE

(1) Procedures for Parent/Caregiver and Child Participants: In Aim 3, the primary parent/caregiver participant will meet with a trained data collector to pilot the baseline assessments of parent- and child-level constructs (see Form M). Some parent forms can be completed on their own, if desired, by being mailed in advance of a face-to-face data collection meeting with research staff. All parent/caregiver participants will also have the option to have all baseline data collection conducted in person with research staff to alleviate literacy or comprehension concerns. Four standardized videotaped parent/child tasks will also be completed. The child participant will also participate in speech, language, and hearing assessments during the in-person meeting with the trained data collector. Data collection for the parent/caregiver and/or the child will be separated into more than one in-person session as needed to prevent fatigue. No data collection will occur unless written informed consent has been obtained.

Approximately one week after piloting the baseline measures, the parent/caregiver and child will participate in the first FCU intervention session, delivered by a trained parent coach in a mutually agreeable location (e.g., participant's home, library, hearing healthcare clinic). The session includes: 1) the Caregiver Report on Family and Self and 2) the Parent Report on Child. These assessments are part of the FCU intervention and will be used to populate the Feedback Form given to families by the parent coach in the second FCU session. The Caregiver Report on Family and Self and the Parent Report on Child are completed either by an online, self-scoring Qualtrics survey or in paper and pencil format (for families who cannot access the online survey), and will not be included as sources of data for analysis of the study by researchers. The parent/caregiver will subsequently engage in up to 6 Family Check-Up sessions total within the next 10 weeks. Each session will last approximately 60 minutes.

Parents/caregivers will be compensated $100 (via mailed check) for completing the battery of assessments, but no compensation will be provided for participation in the FCU sessions. This strategy is intended to make the intervention itself as similar as possible to what

it would be if offered outside of a research protocol, because feasibility of delivering the intervention is a major goal of this aim.

Description of measures for parents/children: The battery of measures (see Form M) is written at an 8th-grade reading level or below. In Aim 3, parent/caregiver participants will pilot our baseline assessments of parent- and child-level constructs, including: a brief sociodemographic background questionnaire (5 minutes); the 100-item CBCL/1.5-5 (20 minutes); the 21-item PARYC (5 minutes); the 19-item PSCS (5 minutes); the 21-item BDI-II (5 minutes); and the 25-item PMI (5 minutes). In our previous studies, completion of a highly similar battery of measures has taken approximately 60-90 minutes, depending on parent literacy level and whether the measures are self- or orally-administered. Parents will also participate in a structured interview with the research assessment to complete the Meaningful Auditory Integration Scale (MAIS), or the Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) if their DHH child is 2 years old.

In addition, we will pilot several key measures of child language development outcomes to parents and children: the Ling sounds test (2 minutes); the repeating familiar sentences task (2 minutes); the PLS-5 (45 minutes); the PPVT (10 minutes); the GFTA (15 minutes); and the BIT (5 minutes). The Ling sounds test and the repeating familiar sentences task will be administered first to verify that the child is hearing. If the child fails these two tasks, additional language measures will not be administered.

Finally, four standardized parent-child interactions will be video-recorded during the baseline assessments: child-directed play, clean-up task, teaching task, and family drawing.

(2) Procedures for Interventionists ("parent coaches"): In Aim 3, following the informed consent procedure, the two parent coaches will pilot pre-training baseline assessments. Next, they will complete a series of training activities including: 1) online, self-paced learning about the Family Check-Up (FCU) program (approximately 8 hours; conducted by the developers of the original FCU), and 2) in-person training (approximately 4 hours) with Dr. Studts for piloting the FCU intervention. Additionally, the parent coaches will complete human subjects protection training, using the CIRTification curriculum (Anderson EE, CIRTification: Community Involvement in Research Training, Center for Clinical and Translational Science. University of Illinois at Chicago, 2011; Available at: www.go.uic.edu/CIRTification), delivered by trained research staff using the facilitator manual, participant workbook, PowerPoint slides, and video vignettes provided by the UIC CTSA. Parent coaches will be included in the IRB's Study Personnel List. Upon completion of all training activities, the parent coaches will complete several additional post-training measures (see Form M).

Following completion of training, each parent coach will deliver the FCU intervention to 1 parent/caregiver-child dyad from the Lexington OCSHCN clinic (with additional caregivers as appropriate), each of whom will have enrolled in the study as described above. The intervention involves meeting with the parent/caregiver participants up to 6 times, with meetings lasting approximately 60 minutes and occurring approximately weekly at mutually agreeable locations. Standard FCU intervention delivery materials will be used for intervention delivery. Parent coaches will receive clinical supervision from Dr. Studts on a weekly basis and more frequently if needed.

All training and intervention delivery activities will be paid at an hourly wage. Parent coaches will be mailed checks for $25 for piloting the battery of baseline assessments, which will take approximately 45 minutes.

Description of measures for interventionists ("parent coaches"): Pre-training baseline assessments for the parent-coaches include a sociodemographic background questionnaire, the 50-item EBPAS, and the 41-item CASES.

Aim 3 data analyses: The small sample size and pilot nature of this aim preclude formal tests of clinical outcomes or attempts to obtain an estimate of an effect size. Thus, data analyses do not focus on differences in parent-, child-, or interventionist-level outcomes pre- and post-intervention. Analyses instead focus on feasibility of planned procedures and are descriptive in nature. First, to assess feasibility, we will determine (a) the proportion of parents agreeing to enroll in the intervention out of all parents approached; (b) the number of sessions attended by each enrolled parent; (c) time required per participant to complete all field-tested instruments and interviews; (e) proportion of missing data across all instruments and within each instrument; and (f) proportions of each full instrument and interview that are successfully completed, to determine the feasibility of including all measures in our future hybrid effectiveness-implementation trial. We are not proposing formal analyses on the results of the other measures because the purpose of this aim is to field-test procedures and measures for Aims 4 and 5.

AIM 4 (EFFECTIVENESS)

Parent/caregiver and child participants in Aim 4 will engage in assessments scheduled every six months over approximately 3.25 years or until the study ends. In addition, participants randomized to the FCU-DHH condition will be offered the FCU-DHH intervention annually (described below). Participants randomized to the treatment-as-usual (TAU) control condition will complete assessments only throughout the course of the study. Research staff conducting data collection will be blinded to participants' random assignment (i.e., FCU-DHH vs. TAU).

(1) Procedures for Parent/Caregiver and Child Participants: In Aim 4, the primary parent/caregiver participant will complete the baseline assessments of parent- and child-level constructs either online via REDCap survey or by mailed paper forms (see Form M and description below). All parent/caregiver participants will also be offered the option to complete assessments with research staff over the phone to alleviate literacy or comprehension concerns. Four standardized videotaped parent/child tasks and a brief parent interview about how the child can hear in various situations will also be completed at baseline, with video captured remotely by HIPAA-compliant videoconferencing software. If parents do not have the capability to connect to videoconference sessions with equipment they own, the research staff will arrange a way to deliver equipment to the family (e.g., drop off equipment while waiting outside, or deliver by certified mail). For participants enrolled after the 3/2/2023 IRB modification/approval (in which participants will not complete any measures past 18-month assessments), the child participant will also participate in baseline speech, language, and hearing assessments with the trained data collector via HIPAA-compliant videoconferencing software (see description of measures, below, as well as Form M). Data collection for the parent/caregiver and/or the child will be separated into more than one session as needed to

prevent fatigue. No data collection will occur unless informed consent has been documented by REDCap or by a mailed copy of a signed paper consent form. Upon completion of baseline data collection, participants will be notified by mailed or emailed letter (according to the parent's preference) of their next steps in the study, depending on whether they were randomized to the FCU-DHH or TAU condition.

Participants randomized to the TAU control condition (n=53 dyads) will receive treatment as usual throughout Aim 4 (i.e., for most, this involves hearing healthcare appointments approximately every 6 months with their practice's providers, which may include nurses, care coordinators, ENT physicians, audiologists, and social workers).

Participants randomized to the intervention condition (FCU-DHH) (n=72 dyads) will be scheduled for their first FCU-DHH session with a trained parent coach within 2 weeks of completing the baseline assessment. Each FCU-DHH session will be delivered by a trained parent coach via videoconference or telephone. Between the first and second FCU-DHH sessions, the parent/caregiver will complete a FCU questionnaire (either online via REDCap survey, by mailed paper forms, or by telephone) that helps the parent coach understand more about the parent and child in the study and about their family context. Additional caregivers may also complete questionnaires if they have provided their consent to participate in the study. These assessments are part of the FCU intervention and will be used to populate the Feedback Form given to families by the parent coach in the second FCU session. The FCU questionnaire will not be included as sources of data for analysis of the study by researchers. If item responses are available from the parent/caregiver's baseline or annual assessments, they will not be re-asked in order to reduce participant burden (e.g., the PARYC items are part of the FCU questionnaire and will not be re-asked of primary participants; additional caregivers will still need to complete these items). The parent/caregiver will subsequently engage in up to 6 Family Check-Up sessions total within the next 4-5 months (total possible = 6 sessions per year). FCU-DHH sessions include one 60-minute assessment session (interview, questionnaires), one 45-minute feedback and motivational interviewing session, and up to four 60-minute skills-training sessions (focused on positive parenting skills such as focused praise, positive reinforcement, effective limit-setting, using consistent consequences).

Parents in either the control or intervention conditions can be referred to additional services within their state that support families with DHH children. For example, a family in either the control or intervention group who expresses a need for services such as social connections with other families of DHH children or a need for assistance in developing an Individualized Education Plan for their child can be referred to their state's Hands & Voices chapter.

Six months after baseline, each primary parent/caregiver participant (in both the TAU and FCU-DHH conditions) will complete follow-up assessments either online via REDCap survey, by mailed paper forms, or by telephone with trained research staff (see Form M and description below). There are no child-level measures administered at the six-month assessments.

Twelve months after baseline, all primary parent/caregiver participants (in both the TAU and FCU-DHH conditions) will complete the one-year follow-up assessments of parent- and child-level constructs either online via REDCap survey, by mailed paper forms, or by telephone with trained research staff (see Form M and description below). Procedures will be identical to those described at baseline; the child's speech, language, and hearing assessments, the parent/child videotaped tasks, and the brief parent interview will be repeated and recorded by HIPAA-compliant videoconferencing software. Parents will repeat the "annual" questionnaires.

Within two weeks of completing the one-year assessment, parent/caregiver participants randomized to the FCU-DHH condition will attend their second round of FCU-DHH sessions, delivered remotely by the trained parent coach via videoconference or telephone. The remaining sessions (up to 6 total) will be delivered within the next 4-5 months. Identical procedures as described at baseline will be conducted with this group. TAU participants will continue to receive treatment as usual.

Eighteen months after baseline, all primary parent/caregiver participants will complete follow-up assessments either online via REDCap survey, by mailed paper forms, or by telephone with trained research staff (see Form M and description below). There are no child-level measures administered at the eighteen-month assessments.

This pattern will continue (annual assessment for all participants + FCU-DHH sessions for FCU-DHH participants only, follow-up six months later for all participants) up to a maximum of 36 months after baseline, or until the study ends (participants enrolling after the 3/2/2023 IRB modification/approval are anticipated to end participation after the 18-month assessment). All data collection will occur remotely. This includes full (i.e. "annual") parent and child assessments at baseline (including child assessments of speech, language, and hearing for participants enrolled after the 3/2/2023 IRB modification/approval),12-month, 24-month and 36-month follow-ups for all participants; reduced (i.e., "mid-year") parent-only assessments at 6-month, 18-month, 30-month follow-ups for all participants; and FCU-DHH sessions for only FCU-DHH participants following the baseline, 12-month, and 24-month assessments). All parents/caregivers will be compensated $75 following the baseline assessments before 3/2/2023 (which do not include child language measures); $100 for baseline assessments after 3/2/2023 (including child language measures) and each annual assessment, and $50 for completing each mid-year assessment. With parental permission, each child will be allowed to select a small age-appropriate toy (stuffed animal, book, puzzle, etc.) following their participation in annual assessments to acknowledge their contribution to the study. No compensation will be provided for participation in the FCU-DHH sessions. This strategy is intended to make the intervention itself as similar as possible to what it would be if offered outside of a research protocol. At the completion of the study, Aim 4 parent participants will receive an additional payment of $100 if all 7 sets of research assessments are completed, an additional $75 if 6 sets of assessments are completed, an additional $50 if 5 sets of assessments are completed, and and an additional $25 if 4 sets of assessments are completed. These amounts are intended to compensate parents for their long-term participation and keep parents engaged even if some assessments are missed.

Description of parent measures: Data collection appointments will be scheduled with each parent-child dyad, on annual and semi-annual basis, as detailed in Form M. All parent/caregiver participants will complete baseline and annual assessments of parent- and child-level constructs, including: a brief sociodemographic background questionnaire also addressing prior healthcare use, child behavior therapy use, and HA/CI adherence (10 minutes); the 100-item CBCL Ages 1.5-5-5 or the 113-item CBCL Ages 6-18 (15

minutes); the 24-item PARYC (10 minutes); the 19-item PSCS (5 minutes); the 21-item BDI-II (5 minutes); the 25-item PMI (10 minutes); and the MacArthur Bates Words & Sentences form (20 minutes) or the MacArthur Bates Words & Gestures form (20 minutes) for children who do not yet produce 10 or more spoken words. Parents will also participate in a structured interview with the data collector to complete the Meaningful Auditory Integration Scale (MAIS); these assessments will be recorded and independently scored by research staff. Parents and children will complete four standardized Family Interaction Tasks (FIT) at baseline and annual assessments which will be videotaped and coded by two observers using (1) the DPICS coding system to provide an additional objective measure of parenting behaviors, and (2) the Systematic Analysis of Language transcripts (SALT) system for assessment of child language production. For families in the FCU-DHH condition, the FIT videos will also be used by parent coaches in feedback sessions. To increase retention during the study, we will also ask parent participants to complete a "Locator Information" form during baseline and annual assessments. The form lists alternative methods that parents agree can be used to locate them if their primary contact information changes or becomes disconnected during the study. During the initial informed consent process, the participant will indicate whether or not they choose to provide this information via an initialed checkbox on the consent document. If yes, either: a) the online survey will be programmed to display the Locator Form questions; b) the data collector will provide the Locator Information form in the mailed packet; or c) the data collector will ask for that information in a phone call. Any data received by mail will be entered into and stored in REDCap, which will be consulted to determine whether or not to provide copies of the Locator Information Form at follow-up assessments. Both the informed consent document and the text at the top of the locator form emphasize that completing the form is optional. If a research staff member uses this form to locate a participant by contacting a relative/friend listed by the participant, care will be taken to only indicate that we are trying to locate the individual in relation to a study. There will be no disclosure of the nature of the study, and therefore, no disclosure of the child's hearing loss.

At each six-month follow-up assessment (i.e., 6 months, 18 months, 30 months), a subset of these parent measures will be repeated, and the FCU-DHH participants will also complete the Therapy Attitude Inventory (TAI; satisfaction measure; 5 minutes). Parent-report language measures will not be administered at the six-month follow-up assessments to reduce participant burden (i.e., MacArthur-Bates, MAIS). There are also no videotaped FIT tasks at six-month follow-up assessments.

Description of child measures: At annual (12-month, 24-month, 36-month, and baseline for participants recruited after 3/2/2023) assessments, we will administer several key measures of child language development outcomes directly to children: the Ling sounds test (2 minutes); the CELF Preschool-3 (ages 3-6) or the CELF-5 (age 7 years and older; 30 minutes - different subtests used for children 7-8 years vs children 9 years and older); the PPVT-5 (15 minutes); and the BIT (5 minutes). The language assessment will be conducted by Zoom videoconferencing and will be recorded to assist in scoring the assessments per their established protocols. Children will participate in videotaped FIT tasks alongside their parent(s), as described above. Language measures will not be administered at the six-month follow-up assessments (i.e., 6-month, 18-month, 30-month).

Additionally, FCU-DHH participants will complete a 20-item set of questions that assesses their satisfaction with their interventionist (SWI - 5 minutes to complete). Each FCU-DHH participant will answer the SWI questions at the assessment timepoint that most closely aligns with the end of their involvement in the study (e.g., participants who enrolled in 2021 will complete these questions at their 36-month assessment; those who enrolled in 2023 will complete these questions at their 18-month assessment because study funding ends in May 2025). In comparison, the TAI assesses satisfaction with the intervention (not the interventionist) and is repeated at 6-month, 18-month, and 30-month assessments.

For all participants, the battery of measures (see Form M) is written at an 8th-grade reading level or below. Data collectors will be trained by the investigators (Dr. Studts for sociodemographic and behavioral measures; Dr. Lowman for speech and language measures) in standardized protocols for administering these measures.

With authorization from the parent/caregiver's signed informed consent document, as well as any other release forms requested by the hearing healthcare practice, OCSHCN and other participating hearing healthcare practices will provide authorized protected health information from medical records to the UK research staff via encrypted email or other means of HIPAA-compliant transfer. A secure REDCap survey will be offered for clinics to use to enter medical information directly, if preferred. Requested data from medical records will include history of prematurity; age of child; type and severity of hearing loss; etiology of hearing loss; family history of hearing loss; other medical or developmental conditions; medical management and surgical history for hearing loss; stability of hearing loss (stable or progressive); age of diagnosis; age of amplification and/or implantation; average daily duration of HA/CI use from data logging technology, if available; and speech therapy history. No data collection from hearing healthcare practices will occur unless written informed consent, HIPAA authorization, and practice-required release forms have been obtained.

Aim 4 data analyses: To make trial arm (FCU-DHH vs. TAU) comparisons, we will utilize linear mixed modeling. In the models, we will utilize random effects corresponding to the interventionists, thus accounting for the possibility of clustering of outcomes from parent-child dyads who received the intervention from the same person. For the analysis of our primary outcome (parenting behaviors as measured by PARYC score at the first 6-month follow-up), a fixed effect for trial arm (FCU-DHH vs. TAU) will be the primary covariate of interest. Additional analyses for Hypotheses 1-4 will address each outcome over time (i.e., PARYC scores as well as continuous measures of child behavior, parent-report and objective adherence with HA/CI, and language development). To account for the correlation among repeated measurements from the same subject, in addition to random effects corresponding to the interventionists, we will also utilize an unstructured within-subject covariance structure. In these multilevel models, trial arm, time (categorical), and their interaction will be used as predictors, with the interaction being of primary interest. All tests will be two-sided with a 5% significance level and will be conducted in SAS Version 9.4 or higher (SAS Institute, Cary, NC). Furthermore, analyses will be based on intention-to-treat.

Principal components analysis and z-scores may be used to create composite language outcomes at each time-point due to the multiple measures proposed, which may reflect a single common trait.100 Note that because rolling study enrollment is necessary (especially in smaller clinics), some parent-child dyads may have fewer observations than others.

We will measure potentially important predictors (e.g., sex, race, parental age, socioeconomic status, degree of hearing impairment, type of hearing rehabilitation device, baseline language development), and statistically compare the balance of the two trial arms. Secondary analyses will include these variables as covariates within the previously described models.

Prior to analyses, we will inspect variable distributions using histograms, probability plots, and residual plots. If necessary, transformations will be performed to make the variable distributions approximate a normal distribution. Alternatively, generalized estimating equations (GEE) may be utilized.

Missing data will be examined to determine the appropriateness of results. We will statistically summarize and compare baseline demographics from subjects who dropped out of the study relative to subjects who did not drop out, and we will look at missing data patterns (e.g., differential dropout). Afterward, using results from these analyses, sensitivity analyses may be conducted following guidelines prescribed by a National Research Council (NRC) report and described in, for example, . Multiple imputation and/or inverse probability weighting may be utilized as necessary.

(2) Procedures for students scoring the BIT speech intelligibility instrument: A private room on the UK campus (e.g., a reserved room at Young Library, an office space or classroom reserved by a member of the Study Personnel) will be used to conduct the informed consent process and the listening exercise with students who volunteer to participate. Upon arrival, the student will complete the informed consent process with the study team member, then the student will be handed a paper scoring document and an iPad with headphones. Sets of 40 audio clips (10 audio clips per child for 4 different children) will be downloaded onto the iPads, as well as 2 practice clips. All audio clips will be identified only by the child's assigned study ID number; no part of any file name or the content of the file will be identifiable. The paper scoring document will be prefilled with the 4 children's study ID numbers, as well as a study ID number assigned to the student. The student's study ID number will never be connected to their name; the sole purpose in creating the student study ID numbers is to be able to connect a student's scoring across the 4 children, in the case that the study team identifies a problem with this student's scoring (and may decide to discard scores for all 4 children). The study team member will provide instruction related to this scoring task (e.g. "listen to each audio clip only twice," "write only the words that you hear") , then the student will complete the practice items. The study team member will clarify any instructions after the practice items are completed, and then allow the student to transcribe what they hear in the 40 audio clips. This is expected to take 15-20 minutes for the student to complete, including the practice items. Study Personnel will record the UK email address for each student who completes the transcription of all 40 audio clips. A $20 Amazon.com gift card will delivered to their UK email address within 2 weeks of their participation.

AIM 5 (IMPLEMENTATION)

In Aim 5, implementation outcomes and factors associated with implementation will be assessed with parent coaches and key stakeholders using quantitative and qualitative methods. Stakeholders identified through our professional networks will complete key informant interviews and quantitative measures with a trained interviewer. Additionally, we will purposively select a subsample of parents with varying outcomes and characteristics who received the FCU-DHH to participate in post-intervention key informant interviews. The semi-structured key informant interviews will seek constructive feedback regarding successes and obstacles to the intervention delivery. Quantitative measures will assess characteristics of the interventionists as well as stakeholders' perceptions of the FCU-DHH.

(1) Procedures for Interventionists ("parent coaches"): In Aim 5, following the informed consent procedure, parent coaches (n=10) will complete training involving: 1) online training to deliver the Family Check-Up (FCU) program (approximately 20-25 hours over multiple days; conducted by an FCU trainer); 2) human subjects protection training using the CIRTification curriculum (as described in Aim 3) (approximately 4 hours); and 3) online training covering adaptations specific to the FCU-DHH program (approximately 5 hours); and 4) additional logistics training (e.g., home visiting safety, mental health "red flags" (See Section 10), data management systems, and reviewing human subjects protection training (approximately 8 hours). Coaches who received the previous phases of training prior to the COVID-19 shutdowns will be re-consented and will be required to complete virtual refresher training courses on all components of training (approximately 12 hours over four days). Parent coaches will be included in the IRB's Study Personnel List. Upon completion of all training activities, the parent coaches will complete a post-training baseline assessment (see Form M and description below).

Adapted FCU-DHH intervention delivery materials will be used for intervention delivery. Parent coaches will receive clinical supervision from a clinical supervisor trained in the FCU (currently Dr. Holzman, a clinical psychologist listed as study personnel through the University of Colorado, a relying IRB site), between all meetings with parents/caregivers. They will also attend bimonthly group supervision meetings with other parent coaches and the clinical supervisor. (Note that any clinical supervisor on the study is also trained in human subjects protection and included in study personnel because they will be interacting with the parent coaches who are research participants and viewing videos of parent/child dyads.) Dr. Studts, who is a licensed clinical social worker, will also be available for back-up supervision and consultation via cell phone. During the phase of intervention delivery, parent coaches will complete monthly online process logs detailing time, attendance, supervision contacts, additional contacts with families, and other expenses associated with intervention delivery. They will also complete fidelity checklists at each appointment with a family. Additionally, one FCU-DHH session per interventionist per year will be video-recorded (with permission from all parties) and coded for fidelity using the COACH rating system created by the original developers of the FCU. Each parent coach will deliver the FCU-DHH to approximately 5-10 families per year.

Following training (or retraining), coaches will complete a battery of measures assessing interventionist-level implementation science constructs. Two weeks after the completion of the final FCU-DHH session with their final families, parent coaches will complete post-intervention assessments (see Form M and description below). Measures used have demonstrated reliability and validity in measuring interventionist and intervention constructs important in implementation science. The research staff will also conduct an audio-recorded,

semi-structured key informant interview with each parent coach aimed at obtaining feedback regarding their experiences with the FCU-DHH and any successes and obstacles to the FCU-DHH intervention delivery.

All training and intervention delivery activities will be paid at an hourly wage. Parent coaches will be mailed checks for $25 at baseline for completing the set of questionnaires which will take about 20 minutes, and they will receive $50 at post-test for completing the final set of questionnaires and the interview, which will take approximately 60 minutes.

Description of parent coach measures: Post-training baseline assessments include sociodemographic background questionnaire assessing sociodemographic characteristics and any work experiences with children/families and/or mental health training/practice; the 15-item EBPAS, assessing attitudes toward evidence-based practice; the 41-item CASES, assessing self-efficacy to deliver the intervention; the 20-item PCIS, assessing perceived characteristics of the intervention; and the 14-item TPA, assessing the acceptability of training and the intervention. Post-intervention quantitative assessments will include the EBPAS, CASES, and PCIS assessments, as well as the 16-item TSI. These are all established quantitative measures in implementation research.

(2) Procedures for Key Stakeholders: At the end of intervention delivery, administrators of the Hands & Voices program or other organizations that support DHH children and/or their families, hearing healthcare providers/administrators, and state-level administrators will complete post-test assessments and will be interviewed by a trained interviewer. Measures administered to administrators will include instruments with demonstrated reliability and validity in measuring contextual constructs important in implementation science. Research staff will also conduct an video- or audio-recorded (per the participant's preference), semi-structured key informant interview with each stakeholder, aimed at obtaining constructive feedback regarding experiences with the FCU-DHH delivery, including successes and obstacles. Administrators will be compensated $50 at post-test for completing the battery of assessments, which will take approximately 90 minutes.

Description of key stakeholder measures: Research staff will conduct an audio-recorded, semi-structured key informant interview with each stakeholder, aimed at obtaining constructive feedback regarding experiences with the FCU-DHH delivery, including successes and obstacles. Key stakeholders will complete a sociodemographic background questionnaire assessing sociodemographic characteristics and level of engagement/awareness with the FCU-DHH intervention. They will also complete the 12-item AIM/IAM/FIM, assessing acceptability, appropriateness, and feasibility of the intervention. These are all established quantitative measures in implementation research.

(3) Procedures for parents: Research staff will conduct an audio-recorded, semi-structured key informant interview with each parent enrolled in Aim 5, aimed at obtaining constructive feedback regarding experiences with receiving the FCU-DHH. Parents who complete key informant interviews will receive $25 (in addition to compensation received in Aim 4).

Data Analyses

For Aim 5, the convergent mixed-methods design will allow simultaneous consideration of quantitative and qualitative data from multiple perspectives to contextualize and gain a more complete understanding of key implementation factors linked with the effectiveness and implementation outcomes of the FCU-DHH. Because this is a type I hybrid trial with a relatively small sample of interventionists and stakeholders, Aim 5 data analyses are primarily descriptive and intended to inform future implementation and scale-up of the FCU-DHH in hearing healthcare settings. Qualitative data analyses will be conducted as described under Aim 2. For quantitative measures of implementation outcomes and factors, descriptive statistics will summarize data within and across the hearing healthcare practices assigned to the intervention condition. If analyses in Aim 4 detect between-coach differences in effectiveness outcomes within the FCU-DHH group, differences in coach-specific implementation outcomes and factors will be examined to identify possible patterns contributing to differential effectiveness. Exploratory analyses targeting implementation outcomes and factors will be conducted between the FCU-DHH clinics regardless of effectiveness outcomes, using models appropriate for the small sample size and levels of data. Qualitative analyses of key informant interviews will be conducted as described in Aim 2.

Attachments

Attach Type	File Name
ResearchProcedures	Satisfaction with Interventionist (SIW) - includes TASCP.docx
ResearchProcedures	CELF5 Ages 9+.pdf
ResearchProcedures	REDCap Screenshots eConsent.docx

Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.
- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

See attached Data Collection Overview form and attached measurement tools and surveys.

**NOTE: Instruments listed in bold italics on the Data Collection Overview Form are not available for review at this time. Each of these instruments will be submitted as a modification request at a future date to be reviewed and approved before being used in the study.

Attachments

Attach Type	File Name
DataCollection	BIT transcription sheet_clean.docx
DataCollection	Data Collection Checklist_Baseline.docx
DataCollection	CBCL 6-18.pdf
DataCollection	MAB_W&S.pdf
DataCollection	Vineland-3.pdf
DataCollection	PPVT-5_FormA.pdf
DataCollection	PPVT-5_FormB.pdf
DataCollection	Coach timelog.pdf
DataCollection	PSAT FINAL.pdf
DataCollection	Focus Group - Hearing Healthcare, SLP, DHH educator.pdf
DataCollection	Semistructured interview guide for parents.docx
DataCollection	CBCL.pdf
DataCollection	PARYC.pdf
DataCollection	PSCS.pdf
DataCollection	BDI-II.pdf
DataCollection	MAIS.pdf
DataCollection	FCU Feedback Form -Rainbow Sheet.pdf
DataCollection	Ling Sounds Test.docx
DataCollection	Clinical Evaluaiton of Language Fundamentals 5.pdf
DataCollection	GFTA.pdf
DataCollection	BIT.pdf
DataCollection	DPICS.pdf
DataCollection	Interventionist Demographics Questionnaire FINAL.docx
DataCollection	Training or Practice Acceptability FINAL - post-training.pdf
DataCollection	EBPAS-50_FINAL - pre training and post intervention.pdf
DataCollection	CASES FINAL - pre and post training and post intervention CHWs.pdf
DataCollection	PCIS - FINAL - post-training CHWs.pdf
DataCollection	FCU_COACHRatingForm - for binder.pdf
DataCollection	TSI_CHW post intervention.pdf
DataCollection	Supervisor log.docx
DataCollection	Coach checklists combined_3.9.20.pdf
DataCollection	Locator Form_MARKED 9.30.21.docx
DataCollection	Locator Form_CLEAN 9.30.21.docx
DataCollection	FCU3-5 redcap.pdf
DataCollection	FCU6-10 redcap.pdf
DataCollection	PMI - revised for CHAMPS-DHH due to control group.docx
DataCollection	PMI - revised CLEAN.docx
DataCollection	TAI_add qual response.pdf
DataCollection	MacArthur-Bates - Words and Gestures.pdf
DataCollection	CELF Preschool.pdf
DataCollection	SALT transcription.pdf
DataCollection	Medical Record Extraction Form.docx
DataCollection	Revised parent background questionnaire_MARKED 10.25.22.docx
DataCollection	Revised parent background questionnaire_CLEAN 10.25.22.docx
DataCollection	interview guide - parents - clean copy - Copy.docx
DataCollection	Coaches Interview Guide_4.29.25.docx
DataCollection	Stakeholder background questionnaire.pdf
DataCollection	Stakeholder AIM FIM IAM.pdf
DataCollection	Stakeholder Interview Guide.docx
DataCollection	Form M_9.5.25_MARKED.docx
DataCollection	Form M_9.25.25_CLEAN.docx

Resources

Describe the availability of the resources and adequacy of the facilities that you will use to perform the research. Such resources may include:

- Staffing and personnel, in terms of availability, number, expertise, and experience;
- Computer or other technological resources, mobile or otherwise, required or created during the conduct of the research;
- Psychological, social, or medical services, including equipment needed to protect subjects, medical monitoring, ancillary care, or counseling or social support services that may be required because of research participation;
- Resources for communication with subjects, such as language translation/interpretation services.

This study will be conducted via collaboration between the study personnel (Dr. Studts at the University of Colorado, Ms. Jacobs and Dr. Bush in the College of Medicine, Dr. Westgate in the College of Public Health, Dr. Lowman in the College of Health Sciences, Dr. Creel at the University of Louisville, and Lori Travis in the OCSHCN). The researchers bring expertise in community-based research, qualitative research, hearing healthcare, speech and language, intervention and dissemination/implementation science, and child behavioral health. The College of Public Health, College of Medicine, College of Health Sciences, and the OCSHCN offer extensive infrastructural resources to ensure support of the project. The Kentucky chapter of the Hands & Voices organization also serves as a key partner in this project, led by Executive Director Sarah Roof. Ms. Roof and a team of her employees will be trained and serve as the interventionists, or "parent coaches" in this project.

Potential Risks & Benefits

Risks

- Describe any potential risks – including physical, psychological, social, legal, ability to re-identify subjects, or other risks. Assess the seriousness and likelihood of each risk.
- Which risks may affect a subject's willingness to participate in the study?
- Describe likely adverse effects of drugs, biologics, devices or procedures participants may encounter while in the study.
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

Benefits

- Describe potential direct benefits to study participants – including diagnostic or therapeutic, physical, psychological or emotional, learning benefits. This cannot include incentives or payments.
- State if there are no direct benefits.
- Describe potential benefits to society and/or general knowledge to be gained.

Describe why potential benefits are reasonable in relation to potential risks. If applicable, justify why risks to vulnerable subjects are reasonable to potential benefits.

Every research study involving human subjects presents some risk; however, there are no known serious risks anticipated from participating in this study. It is possible that parent/caregiver participants may experience some discomfort when responding to questionnaire items about their child's behavior, particularly because some study participants will have children with elevated levels of disruptive behavior problems. If participants experience more serious discomfort, referrals to appropriate counseling resources will be provided using regional mental health service resources lists maintained by our lab.

One risk presented by this study is the breach of confidentiality. For parent participants in Aims 2, 3, 4 and 5, the risks associated with a breach of confidentiality depend on the information released in a breach. A breach of confidentiality revealing study participation, sociodemographic characteristics, a child's behavioral problems, or parent depressive symptoms, for example, may cause the participant to experience discomfort regarding violated privacy, or social consequences such as perceived stigma or judgment by others. A mandated breach of confidentiality (i.e., due to reporting laws about risk of harm to self or others or due to referral to community mental health for suicidal ideation or self-harm) would involve risks associated with potential involvement or investigation by Child Protective Services, Adult Protective Services, law enforcement, or a qualified mental health professional. These potential risks will be explicitly addressed in the informed consent process with parent participants, including written information about these risks in the informed consent documentation. For key stakeholder participants engaged in focus groups or key informant interviews in Aims 2 and 5, the risks associated with breaches of confidentiality primarily involve risks to employment and/or professional relationships. If key stakeholders share negative information about their perceptions of their agencies, colleagues, or organizational leadership in the context of focus groups, it is possible that a breach of confidentiality could put their working relationships or employment status in jeopardy. These risks will be explicitly detailed in the informed consent process with these participants, including written information about these risks in the informed consent documentation.

For parent coach participants in Aims 3 and 5, the risks associated with breaches of confidentiality primarily involve risks to employment and/or professional or personal relationships. If parent coaches share negative information about their perceptions of their agencies, colleagues, or organizational leadership in the context of the assessments in Aims 3 and 5, it is possible that a breach of confidentiality could put their working relationships or employment status in jeopardy. These risks will be explicitly detailed in the informed consent process with these participants, including written information about these risks in the informed consent documentation.

There may also be risks associated with the delivery of a behavioral intervention. All parent coaches will complete the FCU-DHH and human subjects protection training, and they will engage in weekly clinical supervision via videoconferencing plus as-needed individual clinical consultation in person or by phone with the experienced and licensed clinical supervisor who is additionally trained as a trainer, supervisor, and provider for the Family Check-Up intervention. See the section below on protection against risks for specific protocols in place to ensure appropriate referrals to specialty mental health care are made when needed.

Many precautions are planned to guard against violations of participant confidentiality, described below. Unavoidable mandated breaches of confidentiality would be related to participant disclosure of imminent risk of harm to self or others, including child abuse or suicidality, to study staff, including data collectors or interventionists. By state law, such statements must be reported to the appropriate authorities. These risks to maintaining confidentiality will be explained explicitly in the informed consent procedures conducted with all participants.

In Aims 3 and 4, we will explicitly detail the risks associated with delivery of services by parent coaches in the informed consent process with parent/caregiver participants, including written documentation of these risks in the informed consent documentation. Specifically, the risks associated with delivery of services by parent coaches include the possibility that the quality of services will not be as high as services delivered by mental health professionals due to parent coaches' limited training in early childhood and family behavioral health. There is a risk that services delivered by a parent coach could be harmful (i.e., result in more child behavior problems) rather than helpful. In addition, there is a risk that an issue requiring more intensive or a different type of treatment may not be identified by a parent coach as readily as it may be by a trained mental health professional. The provision of training and continued clinical supervision is intended to minimize these risks.
Participation in the study involves minimal risk for subjects in comparison to the potential benefits of adapting a behavioral parent training intervention for parents of preschool-aged DHH children. During the informed consent procedures, participants will be informed they may not experience direct benefits from participating in the project. However, they will be reminded that they are assisting in adapting and evaluating an evidence-based intervention for parents of DHH children. After the 24-, and 36-month annual assessments, parents in both conditions (FCU-DHH and TAU) will be provided with a summary of their child's progress in language assessments from the previous year. Additionally, the parent coaches may benefit from the skills and information provided as part of the FCU-DHH intervention. We believe that this potential overall benefit outweighs the minimal risks associated with the study procedures.

Available Alternative Opportunities/Treatments

Describe alternative treatments or opportunities that might be available to those who choose not to participate in the study, and which offer the subject equal or greater advantages. If applicable, this should include a discussion of the current standard of care treatment(s).

If potential participants choose not to participate in the study, there are no available alternative treatments.

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Records, Privacy, and Confidentiality

Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Specify who will have access to the data/specimens and why they need access.

Describe how data will be managed after the study is complete:

- If data/specimens will be maintained, specify whether identifiers will be removed from the maintained information/material.
- If identifiers will not be removed, provide justification for retaining them and describe how you will protect confidentiality.
- If the data/specimens will be destroyed, verify that this will not violate retention policies and will adhere to applicable facility requirements.

If this study will use de-identified data from another source, describe what measures will be taken to ensure that subject identifiers are not given to the investigator.

If applicable, describe procedures for sharing data/specimens with collaborators not affiliated with UK.

For additional considerations:
Return of Research Results or Incidental Research Findings
HIPAA policies
FERPA policies
Procedures for Transfer agreements
Information regarding multi-site studies
NIH Genomic Data Sharing (GDS) Policy
Digital Data

Research data will be obtained from human subjects in the form of semi-structured key informant interviews and focus groups, paper-and-pencil questionnaires, online (Qualtrics and REDCap) questionnaires, audio files, and videotaped tasks or sessions. Data from paper-and-pencil surveys will be entered into a REDCap database. With parent permission and signing an additional release of information specific to their hearing healthcare practice, some data will be obtained from hearing healthcare practices. All adult research participants will be asked to provide written informed consent during initial recruitment; parents will provide informed consent for participating children between the ages of 2 and 6, and children ages 6 to 9 will provide verbal assent.

All study documentation (i.e., paper-based questionnaires; online questionnaires; interview notes; audio-tapes of interviews and focus groups; transcripts of audiotapes; and videotaped sessions) will be coded using participant ID numbers rather than names or other identifying information. An electronic link file of participant IDs and names will be securely maintained via REDCap. Any transfer of electronic files between the hearing healthcare clinics and the UK campus research team members will be completed using HIPAA-compliant encrypted file transfer. All electronic files, regardless of identifiers, will be accessible only by IRB-approved and human subjects protection-trained study staff. Transfer of hard copies of research documents between meeting sites with participants and the UK campus investigators will be via a lockbox and then stored in a locked cabinet in the research office. Audio files and videos of parent-child FIT tasks and of FCU-DHH sessions for fidelity ratings will be captured by data collectors either on password-protected iPads set up and maintained by UK IT or by HIPAA-compliant videoconferencing software (e.g., Zoom or Microsoft Teams). Data collectors will upload these files to secure OneDrive shared folders with permissions and access maintained by the UK PI. This will provide a secure means of transferring video files between data collectors, parent coaches, clinical supervisors, and research staff for

the purposes of clinical supervision and coding of observational data. Once uploaded, videos will be deleted from the tablets. Research documents including participant identifying information (e.g., informed consent documents, signed receipts for participant payments) will be stored separately from data documents.

As stated above under section 10 (Safety Precautions), the risk associated with mandatory reporting laws and need to protect participants who express suicidal ideation with a plan and means will be emphasized explicitly to all participants during the informed consent process. In addition, because key stakeholder participants in Aim 2 focus groups may be at increased risk of breaches of confidentiality (because their participation includes interactions with other participants), this risk will be highlighted in these groups' informed consent documents. Further, this risk will be reviewed prior to each focus group, and participants will be asked to respect the confidentiality of their fellow attendees. See "Safety Precautions" for additional details regarding security of audio and video recordings and transcripts of participant interviews and focus groups. At the completion of the study, all research documents will be stored securely in a locked cabinet in the research office space (for hard copies) or in password-protected files on a secure UK server (for electronic files) for 6 years after the end of the project, then destroyed.

Confidentiality of all data will be maintained by using REDCap -- a HIPAA-compliant, password-protected, secure web-based platform – as the only link between participants' identifying information (names, contact information) and their data (questionnaires, assessments). Access to REDCap projects will be maintained by the UK PI Julie Jacobs, and only research staff with current certification in human subjects protection will be allowed access to the minimum amount of data required to perform their role in the project. Video and audio files will be stored on the HIPAA-compliant cloud server, OneDrive, available via UK's contract with Microsoft. Through careful OneDrive permissions controlled by the UK PI Ms. Jacobs, only HSP-trained research staff will have access to the link file via secure, personalized access links. Hard copies of paper-based informed consent documents and questionnaires will be mailed directly to the research office. They will subsequently be stored in locked filing cabinets in the research office on the UK campus. Documents containing names (e.g., informed consent forms) will be physically stored separately from those containing data. Audio- and video-taped assessments will be captured using iPads set up and maintained by UK's Facilities Information Services (FIS) and/or by UK Zoom accounts. UK FIS will remotely control the set-up of all iPads at all times and has the ability to lock and/or erase any iPad in the event it is lost or stolen. All iPads are secured with individual passcodes and touch ID. Audio and video recordings and scanned documents will be securely uploaded to OneDrive via the iPad application. Files will be named using an assigned ID number. Recordings will be deleted from the iPads as soon as uploading is verified and complete. Transcripts of recordings will be named and stored securely in the same way, with any spoken names and identifying information redacted from the typed content of the interview. Hard copies of transcripts of interviews will be labeled only with assigned ID numbers and stored in a locked file cabinet in the research office. Parent coaches, who are employees of our partnering organization Kentucky Hands & Voices, have received UK linkblue IDs in order to securely access files through UK's OneDrive in the same manner as UK staff. They will not have access to REDCap. However, given the potential for parent coaches to know other families in the DHH community, file permissions for parent coaches will be carefully controlled to only allow each coach to only view contact information and video-taped assessments (a required element of the FCU-DHH intervention) for the individual families they are assigned to visit. At the completion of the study, all research documents (including consent forms, questionnaires, audio-recordings, and electronic and hard copies of transcripts) will be stored securely electronically (as described above) or in a locked cabinet in the research office space for 6 years after the end of the project, depending on whether the document is in a hard copy or electronic copy format.

Certain protocols will be in place to address the potential risks associated with provision of services by parent coaches, rather than by mental health specialists. As a precaution, a letter signed by Dr. Studts or Ms. Jacobs will be sent to families with either (1) a child scoring at the 90th percentile or above on the CBCL internalizing or externalizing subscales at any assessment time point, or (2) a parent/caregiver indicating a "moderate" or higher level of depression according to scoring guidelines of the BDI-II at any assessment time-point. The letter will provide a referral to a local community mental health center for evaluation (as these families may be experiencing an immediate need for mental health services rather than only our brief preventive intervention). Families requesting more intensive services will be referred to the local community mental health center. Need for referral will be determined via parent coaches' feedback with the clinical supervisor during ongoing supervision, as well as by Ms. Jacobs' and Dr. Studts's review of child- and parent-level outcomes as they are assessed.

The rigor of the existing training curriculum for the evidence-based Family Check-Up (FCU) is a protection against risk associated with delivery of a behavioral intervention. The FCU training covers the empirical evidence and foundation for the intervention; motivational interviewing techniques; systematic, ecologically based assessments of family strengths and needs; provision of assessment-based motivational feedback; social cognitive and behavioral principles underlying skills training; and strategies for teaching and practicing 3 core parent practices (positive behavior support, limit-setting, and relationship-building). A combination of didactic, discussion, modeling, and role-play activities are used. It also is worth noting that the empirical basis for requiring mental health professionals as interventionists for behavioral parent training is not conclusive; for example, Lavigne and colleagues (2008) reported comparable effects of self-study, nurse-led, and psychologist-led delivery of the Incredible Years program in treating oppositional defiant disorder in primary care. Innovative programs training paraprofessionals to deliver these interventions (even including parents training parents) also have been described and favorably evaluated [e.g., see Roberts, (Ed.), 1996, Model Programs in Child and Family Mental Health]. Determining whether we can train and supervise parent coaches to deliver this intervention with fidelity is one of the primary goals of the study.

Research staff and parent coaches will complete online human subjects protection training prior to their in-person training with Dr. Studts and other members of the research team. The in-person training of research staff and parent coaches will include sessions on: 1) home visiting safety, 2) signs of child abuse/neglect and mandatory reporting requirements and procedures, 3) mental health "red flags" that require immediate follow-up, including suicidality, and 4) a review of patient confidentiality, HIPAA, and other elements of human subjects protection (in addition to completion of online CITI training, or CIRTification training for parent coaches) as they specifically relate to this project. Dr. Studts and her team successfully delivered this set of trainings in February 2017 to community health workers (CHWs) in the ongoing trial of CHW-delivered FCU sessions to families in rural Appalachia with no adverse events or other problems occurring in the following 13 months of FCU delivery. The content of the trainings is based on the FCU training

protocols as well as existing trainings and protocols of the Kentucky Department for Public Health, the HANDS Home Visiting Health and Safety Protocol, the Kentucky CHFS Department for Community Based Services, and UK's Center for Excellence in Rural Health's Kentucky Homeplace program.

Regarding mandatory reporting of suspected child abuse or neglect, all adults in Kentucky are mandated reporters according to KRS 620.030 (1), and the same protocol will be used for all families enrolled in the study, regardless of the state where the family is located or the location of the reporter (i.e., the research staff member or parent coach). Our procedures will follow a "chain of command" protocol in which the research staff member or parent coach who suspects or has witnessed abuse or neglect documents the incident on a standard template and contacts their supervisor immediately (Ms. Jacobs for research staff, the clinical supervisor (currently Dr. Holzman) for parent coaches, each of whom will collaborate with Dr. Studts to determine the best course of action in each unique situation). Research staff and parent coaches will be trained in mandatory reporting requirements and may make reports directly to Child Protective Services (CPS) or to 911 if indicated. As supervisors and mandatory reporters, Ms. Jacobs or the clinical supervisor will be responsible for following up with study staff to ensure that the report was made; if needed, the supervisors will make the report themselves, documenting the report and other relevant information. Any required confidentiality violations occurring due to mandated reporting will be reported by Ms. Jacobs as an adverse event (see "Reporting of adverse events" section below). This chain of command protocol is favored as it supports the research staff member or the parent coach in making the report themselves or working with Ms. Jacobs or the clinical supervisor to ensure the report is made. Our training curriculum will include specific procedures for research staff, parent coaches, the clinical supervisor, and the PI requirements to report. These protocols will include examples of reportable circumstances, required timeframes, responsibility for specific tasks (e.g., seeking and providing supervision, documentation, initiating reports), and expectations for communication and confidentiality. The risk associated with mandatory reporting laws will be emphasized explicitly to all participants during the informed consent process. Data collectors and parent coaches will be provided with both a laminated hard-copy and an electronic copy of a "CHAMPS-DHH Safety Protocols" documents, with one side dedicated to Child Abuse or Neglect, and the other to Suicidality (see Safety Protocols in Additional Information). They will also be provided with geographically specific emergency and CPS phone numbers for each family before beginning online meetings with the family (e.g., for a family that resides in Colorado, the "24/7" Colorado CPH hotline number will be stored in REDCap for data collectors and in OneDrive for parent coaches, which are the systems they currently use to access family information). The laminated safety protocol sheet is intended as a backup system in case of emergencies or lack of immediate access to REDCap or OneDrive (e.g., a team member can quickly re-access state-specific CPS agency information via the national phone number or website). A Kentucky-specific safety protocol will be provided to data collectors and parent coaches who work with larger numbers of Kentucky families, from the beginning of the study.

Regarding mental health "red flags", research staff members and parent coaches will be trained to recognize common signs and symptoms of child and adult mental health issues which may require additional intervention. Research staff will be trained to contact Ms. Jacobs if they observe red flags in child or parent participants. Parent coaches will be trained to contact their clinical supervisor if they observe red flags. Ms. Jacobs and the clinical supervisor will collaborate with Dr. Studts to determine the best course of action in each unique case. In these cases, we maintain a list of county-specific mental health and substance abuse treatment organizations for study staff to share with participants.

Regarding suicidality (i.e., statements of suicidal ideation and/or any response >0 on the suicidal ideation item on the BDI-II), research staff and parent coaches will be trained in a question-persuade-refer model with actions dependent on level of risk (see Additional Information attachments for "CHAMPS-DHH Safety Protocols" for Child Abuse/Neglect and Suicidality). REDCap will be programmed to automatically email an alert to Dr. Studts, Ms. Jacobs and other research staff if the BDI questionnaire indicates suicidal thoughts or wishes. In all cases of encountering suicidal ideation, research staff and parent coaches will contact Dr. Studts and Ms. Jacobs as soon as possible after completing the listed steps. The situation will be documented and if confidentiality was broken, the adverse event will be reported as outlined under "Reporting Adverse Events," below.

In our previous studies with parents and children, we have very rarely encountered situations necessitating mandatory reporting or seeking assistance for suicidality. Parents who enroll in the study are aware and willing to have data collectors and interventionists meet with them and their children, so the study sample may be of lower risk than the general population. However, this training and support will be provided to all research staff and parent coaches so that all are prepared for these scenarios, no matter how unlikely they may be.

☑ **UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Check this item to confirm that you will retain all IRB-related records for a minimum of 6 years after study closure.**

Payment

Describe the incentives (monetary or other) being offered to subjects for their participation. If monetary compensation is offered, indicate the amount and describe the terms and schedule of payment. Please review this guidance for more information on payments to subjects, including restrictions and expectations.

Parent/Caregiver and Key Stakeholder participants in Aim 2 will be given $25 via mailed check (an amount commensurate with our previous studies) for participating in key informant interviews and focus groups. Parent/Caregiver participants in Aim 3 will be given $100 via mailed check for baseline assessments. Parent/Caregiver participants in Aim 4 will be given $100 at baseline (changed with 3/1/2023 modification to add child language measures to baseline), $100 annually for assessment sessions, as well as $50 semi-annually for six-month follow-up assessment sessions. Child participants in Aim 4 will be allowed to select an age-appropriate toy upon completion of their annual assessments, with the permission of their parents. As a end-of-study bonus to encourage study retention, Aim 4 parent participants will receive an additional payment of $100 if all 7 sets of research assessments are completed, an additional $75 if 6 sets of assessments are completed, an additional $50 if 5 sets of assessments are completed, and an additional $25 if 4 sets of assessments are completed. These amounts are intended to compensate parents for their long-term participation and keep

parents engaged even if some assessments are missed. Parent coaches in Aims 3 and 5 will be given $25 for baseline and post-intervention assessments and $50 for post-intervention assessments in Aim 5. Administrator/provider key stakeholders in Aim 5 will be given $50 for participation in assessments, and Aim 5 parent participants will be given $25 for their participation in an interview (in addition to their Aim 4 payments). Students who score the BIT speech intelligibility instrument will receive a $20 gift card about 1-2 weeks after completing their research task.

Costs to Subjects

Include a list of services and/or tests that will not be paid for by the sponsor and/or the study (e.g., MRI, HIV). Keep in mind that a subject will not know what is “standard” – and thus not covered by the sponsor/study – unless you tell them.

There are no costs associated with participation in the study, apart from possible transportation costs to the interview locations and internet or telephone fees for connecting to virtual appointments. Parent/caregiver and key stakeholder participants will be responsible for their own travel costs and internet/telephone fees. If a participant would incur a charge for any phone call or videoconference and our research team is made aware prior to the appointment, we will work with the participant to find an agreeable option that will be free to the participant.

Data and Safety Monitoring

The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research or NIH-funded/FDA-regulated clinical investigations.

- If you are conducting greater than minimal risk research, or your clinical investigation is NIH-funded, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.
- If this is a non-sponsored investigator-initiated protocol considered greater than minimal risk research, and if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

We have two Data and Safety Monitoring plans: a DSMP for Aims 2, 3, and 5, and a DSMB for Aim 4, which is categorized as a clinical trial by NIH. Both are described below.

In addition to complying with NIH guidelines, our DSMP complies with the UK Institutional Review Board (IRB) and UK Office of Research Integrity (ORI) SOPs (http://www.research.uky.edu/ori/) for implementation of data and safety monitoring (http://www.research.uky.edu/ori/human/SOPs_&_Policies.htm).

Risk assessment: Minimal risk:
All aspects of the proposed research involve minimal risk. We will be collecting data via key informant interviews, questionnaires, and focus groups. All study personnel (i.e., investigators, study coordinator, research assistants, data collectors, parent coaches) will be trained in the protection of human subjects, and all data collection and management procedures have been designed to minimize the risk of a confidentiality breach.

Description of potential adverse events:
Possible serious adverse events (SAEs) include: disclosures of abuse, neglect, domestic violence, or suicidal ideation. Unanticipated problems that are not SAEs include but are not limited to breach of confidentiality of study data, distress about answering questions about child behavior, and unanticipated negative reactions concurrent with or following study procedures. Protocol violations and instances of non-compliance include any deviations from the study protocol and/or the human subjects protection plan as approved by the IRB.

Description of safety monitoring for Aims 2, 3, and 5:
The study will involve 71 participants in Aims 2, 3, and 5, including 20 parents and 15 key stakeholders in Aim 2; 2 parents, 2 children, and 2 parent coaches in Aim 3; and 10 parent coaches, 10 hearing healthcare administrator/providers, and 10 parents who completed the intervention in Aim 5. We will conduct no medically intrusive screenings or interventions. SAEs, unanticipated problems, protocol violation, and instances of non-compliance may each become known from a variety of sources, including participant self-report, study staff report, data collected, or reports to any member of the research team from community partners or members.

The investigators on this project have extensive experience working in communities and have had no safety concerns in the past. It is possible that some psychological distress will result from completing the study procedures. Lists of local counseling resources will be made available to all parent/child participants. If the participant experiences psychological discomfort with the assessments or study procedures, he or she will be reminded by trained data collectors and/or parent coaches that she need not complete the protocol and has the right to withdraw from the study at any time.

Another potential risk in this study involves loss of confidentiality. Our data collection and monitoring protocols, described in above sections, will minimize this risk. In the case of mandatory reporting of child abuse or neglect and potential referral to an emergency room for evaluation of suicidality, we will ensure via the informed consent process that all participants are fully informed of this risk.

All adverse events (AE) will be immediately reported to the UK PI, Ms. Jacobs, who will be responsible for (1) reporting AE to the IRB, (2) evaluating all AE and determining whether the AE affects the risk/benefit ratio of the project, and (3) determining whether changes need to be made to the protocol and informed consent documents. All staff, including RAs, data collectors, the clinical supervisor, and

parent coaches, will be trained to recognize an AE and to undertake the proper reporting protocols in the event of an AE. Additionally, the study PI Dr. Studts, and Co-Investigators Dr. Bush, Dr. Lowman, and Ms. Travis will participate in the monitoring of the safety of the participants. These study personnel will meet as a team every six months and produce a written report that summarizes all items to be monitored, as follows:

Items to be monitored by the DSMP:
Eligibility - All subjects enrolled in a study are confirmed for eligibility by an independent person with expertise prior to enrolling the subject into the study.
Consent - Consent review is included in the eligibility process. This includes verifying an open study, current consent, and appropriate execution of the consent.
Reconsent - The research team receives a notification of all approved amendments for a study. If the amendment addressed the consent, it is determined prior to the notification whether reconsent is mandatory. If so, the research team is notified that they must reconsent subjects.
Data Quality - This verification includes monitoring for timeliness and accuracy of data input.
Accrual - Evaluation of the quality of ongoing study conduct by reviewing the study accrual.
Adverse Events - Review of all adverse events to assure the safety of human subjects.
External Factors and Ethics - Consideration of factors external to the study when relevant information becomes available, such as scientific developments that may have an impact on the safety of the subjects or the ethics of the study.

Reporting of adverse events:
Our procedures and timeframe for reporting SAEs, unanticipated problems, protocol violations, and instances of non-compliance are based upon guidance available from OHRP (http://www.hhs.gov/ohrp/policy/advevntguid.html), and literature focused on data safety and monitoring in social and behavioral clinical research [e.g., Czaja et al. (2006), Data and safety monitoring in social behavioral intervention trials: the Reach II experience. Clinical Trials, 3, 107-118; Horigian et al. (2010), Principles for defining adverse events in behavioral intervention research: lessons from a family-focused adolescent drug abuse trial. Clinical Trials, 7, 58-68].

Commensurate with OHRP recommendations, reports of each of these types of event will be made by study staff immediately (i.e., within 24 hours) to the PI for her review and classification using three questions: (1) Is the event unexpected? (2) Is it related or possibly related to participation in the research? and (3) Does it suggest that the research places participants or others at a greater risk of harm than was previously anticipated or recognized? Reporting to the PI will be completed by study staff using a standardized form recording the date of the event, type of event, attribution of the event to the research procedures (to be initially determined by the PI during follow-up investigation), whether the event was resolved, and resolution date. Ms. Jacobs, as the PI and lead safety monitor for the DSMP (see DSMP section below), will subsequently report the event to the University of Kentucky IRB, per 45 CFR 46.103b5. This report will include: (1) the appropriate identifying information for the research protocol; (2) a detailed description of the event; (3) an explanation of the basis for determining that the event represents an unanticipated problem; and (4) a description of any protocol changes or corrective action proposed or taken in response. In the case of SAEs found to be related to the research procedures, the PI will follow University of Kentucky procedures on critical incident review. The study protocol also will include necessary steps regarding staff and participant debriefing in the case of an SAE related to research procedures. Regarding timing of reports to the IRB, every effort will be made to complete prompt reports as quickly as possible, using OHRP recommendations as latest possible deadlines (i.e., unanticipated problems that are SAEs reported to IRB within one week of PI becoming aware; any other unanticipated problems reported to IRB within two weeks of PI becoming aware; all unanticipated problems reported to appropriate UK officials within one month of the IRB's receipt of the report from the PI). Ms. Jacobs will also prepare the summary of all Adverse Events for the project's duration. The written SAE report will also be sent to the University Of Kentucky Office Of Research Integrity Director. Any severe AE will be reported immediately. Because of the minimal level of risk of the proposed project, we have not created a Data Safety and Monitoring Board.

Reporting of other study-safety events:
As the study is being conducted, the PI will also inform the IRB promptly of any changes in recruitment or in the protocol that are relevant to safety. In the event of any changes in the status of an ongoing protocol, the PI will inform the IRB immediately. Such changes would include:
• Amendments to the protocol
• Temporary suspension of participant accrual, or of the protocol
• Any change in informed consent or IRB approval status
• Termination of participant accrual, or of the protocol
• Other problems or issues that could affect the human subjects in the study

Data confidentiality, protection, and monitoring:
All activities concerning data and human subjects protection will be approved by the University of Kentucky
IRB with the following requirements:
• All participants must understand, agree to, and sign a consent form before participating.
• Strict adherence to a participant's right to withdraw or refuse to answer questions is maintained.
• The interviews and questionnaires are completely confidential and no names will be associated with the interviews or intervention activities. In all instances, the data files do not contain the name of the participant. Instead, each participant is assigned a unique four-digit identifying number.
• Data will be secured. A computer file linking the unique number with the participant's name will be kept in the PI's office and hard copies of documents will be stored in locked file cabinets, separating identifiers from interview/questionnaire responses. All computer data will be stored on secure servers with access limited to approved human subjects protection-trained study personnel.
• At no time will a person who is not study staff be permitted to review identifying data.
• All identifying information will be kept locked at all times, including during transportation between the study site and the PI's office via lockboxes.

• All documentation of IRB approval, original consents, human participants certification for staff, and other related study information will be filed and easily accessible to the PI.
• All study personnel must successfully complete the CITI or Protecting Study Volunteers in Research Certification.

Description of Safety Monitoring for Aim 4:
Because this study will adapt and compare a behavioral intervention to a treatment as usual approach, treatment allocations are randomly assigned, and children are involved, we consider the trial a Phase III study and will implement a Data Safety and Monitoring Board (DSMB).

Risk assessment: Minimal risk
All aspects of the proposed research involve minimal risk. We will be conducting key informant interviews, obtaining self-report questionnaire and interview data, obtaining clinical history and measures of hearing, and conducting a hybrid effectiveness-implementation trial of the FCU-DHH with patients followed in hearing healthcare practices across the state. All study personnel (i.e., investigators, study coordinator, interviewers, and interventionists) will be trained in the protection of human subjects, and all data collection and management procedures have been designed to minimize the risk of a confidentiality breach. However, due to the involvement of children and the Phase III nature of the study design, we will retain a DSMB.

Description of potential adverse events

Possible serious adverse events (SAEs) include:
• Abuse
• Suicidal behavior
• Homicidal behavior
• Emergency room visits
• Hospitalization (psychiatric or otherwise)
• Death

Unanticipated problems that are not SAEs include but are not limited to:
• Expulsion from preschool or daycare
• Runaway
• Dissolution of family unit (i.e., separation, divorce, or out-of-home placement)
• Suicidal ideation
• Breach of confidentiality of study data (including required breach of confidentiality due to domestic violence and/or child abuse reporting laws)
• Distress about answering questions about child behavior
• Unanticipated negative reactions concurrent with or following study procedures

Protocol violations and instances of non-compliance include any deviations from the study protocol and/or the human subjects protection plan as approved by the IRB.

Description of safety monitoring
The DSMB will monitor data from the 125 parent-child dyads in Aim 4. We will conduct no medically intrusive screenings or interventions. SAEs, unanticipated problems, protocol violation, and instances of non-compliance may each become known from a variety of sources, including participant self-report, study staff report, data collected during baseline and post-test assessments, or reports to any member of the research team from community partners or members.

The main investigators on this project—Dr. Studts, Dr. Bush, Dr. Westgate, Dr. Lowman, Dr. Travis, and Dr. Creel—have extensive experience working with the DHH target population and have had no safety concerns in the past. It is possible that some psychological distress will result from completing the questionnaires. While this is extremely rare, our lab has established names and contact information for counseling services across the state. If a participant is in need of counseling, all she or he need do is to inform any study staff, who will inform Dr. Studts, who will provide an appropriate referral. If a participant experiences psychological discomfort with the assessment, s/he will be reminded that s/he need not complete the protocol and has the right to withdraw from the study at any time. Research assistants with direct participant contact will be trained in recognizing and reporting this occurrence.

Another potential risk in this study involves loss of confidentiality. Our data collection and monitoring protocols, described in above sections, will minimize this risk. In the case of mandatory reporting of domestic violence and/or child abuse and neglect and potential emergency room referral for evaluation of suicidality, we will ensure via the informed consent process that all participants are fully informed of this risk, and we have trained all study staff in protocols for responding to these risks.

The potential risks associated with provision of a behavioral intervention will be minimized with specific safety monitoring and precautions. Families with children scoring at the 90th percentile or above on the CBCL/1.5-5 at any assessment time point (i.e., at baseline or post-test) will be referred to the community mental health center for evaluation (as these children may require more intensive services). Similarly, any participants who endorse or report suicidal ideation or self-harm will be referred to the local emergency room for evaluation. Families requesting more intensive services also will be referred. Need for referral will be determined via parent coach report during clinical supervision, as well as by the PI's review of child- and parent-level outcomes as they are assessed.

All adverse events (AE) will be immediately reported to the PI, Dr. Studts, who will be responsible for (1) reporting AE to the UK IRB, DSMB, and NIDCD, (2) assisting the DSMB with evaluation of all AE and determining whether the AE affects the risk/benefit ratio of the project, and (3) assisting the DSMB with determination of whether changes need to be made to the protocol and informed consent documents. All staff, including RAs, interviewers and interventionists, will be trained to recognize an AE and to undertake the proper reporting protocols in the event of an AE. Additionally, study Co-Investigators and the UK site PI, Ms. Jacobs, will participate in the monitoring of the safety of the participants. These study personnel will meet as a team every six months and produce a written report that summarizes all items to be monitored, as follows:

Responsibilities of the DSMB
• Review and approve the research protocol(s) and plans for data and safety monitoring. The DSMB, in collaboration with the PI, will establish specific guidelines for safety monitoring. This will include a listing of events that should be reported immediately to the DSMB and the format of reporting cumulative data at intervals.
• Review interim analyses of outcome data for safety and efficacy to determine whether the study should continue as originally designed, be changed, or be terminated. The DSMB will review clinical study performance information such as participant recruitment and retention, clinical center and resource center performance, and proposals for ancillary studies. It will advise the investigators and the NIDCD on these topics. The DSMB will also recommend whether and to whom outcome results should be released prior to the reporting of study results.
• Review the primary study abstract(s) and manuscript(s) with regard to determining that the results are fairly presented and the conclusions appropriate.
• Review published reports of related studies submitted to it by the NIDCD, the study leadership/investigators, or DSMB members to determine whether the monitored study needs to be changed or terminated.
• Review proposed modifications to the study prior to their implementation (e.g., increasing target sample size, dropping an arm based on other study outcomes, modifying outcomes, etc.).
• As soon as possible but within 10 business days following each DSMB meeting, provide the study leadership and the NIDCD with DRAFT written recommendations along with justification related to continuing, changing, or terminating the study.
• As soon as possible but within 10 business days following each DSMB meeting, provide the study leadership and the NIDCD with a statement, where appropriate, concerning the impact on the study of individually observed or cumulative adverse events.
Confidential outcome data will not be made available to individuals outside of the DSMB. Any release of outcome data to individuals outside of the DSMB will be reviewed and approved by the DSMB, the NIDCD, and the study leadership. No communication, either written or oral, of the deliberations or recommendations of the DSMB will be made outside of the DSMB except as provided for in these guidelines. Outcome results will be strictly confidential and will not be divulged to any non-member of the DSMB. Each member of the DSMB, including non-voting members, will sign a statement of confidentiality.
DSMB Membership
We will utilize the standing independent Data Safety Monitoring Board (DSMB) as chartered by the University of Kentucky Center for Clinical and Translational Science (CCTS) to monitor the safety of this study. Individuals on the DSMB will disclose any potential conflicts of interest, whether real or perceived, to the NIDCD program director on an annual basis. The NIDCD and the study leadership will make collaborative decisions regarding service by individuals with potential conflicts of interest or the appearance of conflicts of interest.

Meetings
The DSMB will meet semiannually or as needed, and will review subject recruitment, AE's, side effects, withdrawals, protocol violations, and inclusion/exclusion criteria. More frequent meetings will take place if necessary. Procedures and reports will follow NIDCD requirements for DSMB.

Reporting of adverse events
Our reporting plan follows NIDCD guidelines, which are based on 1996 and 2000 International Conferences on Harmonization, sections E2 and E6 Good Clinical Practice, and Health and Human Services (HHS) and FDA regulations. The UK Medical IRB has ultimate authority in assessing, managing, and reporting adverse events. Reporting of AEs to the PI will be completed by study staff using a standardized form recording the date of the event, type of event, whether the event was resolved, and resolution date.

The PI will report by telephone, fax, or email all deaths and life-threatening SAEs within 24 hours to the NIDCD program officer and to the UK IRB as specified in the protocol. This immediate report will be followed within 7 days by a detailed written report from the study coordinator or principal investigator to the NIDCD, IRB, and all participating investigators. All other SAEs will be reported to the NIDCD within 7 days, followed by a detailed written report to the NIDCD, IRB, and all participating investigators within 15 days. This report will include: (1) the appropriate identifying information for the research protocol; (2) a detailed description of the event; (3) an explanation of the basis for determining that the event represents an unanticipated problem; and (4) a description of any protocol changes or corrective action proposed or taken in response. In the case of SAEs found to be related to the research procedures, the PI will follow University of Kentucky procedures on critical incident review. The study protocol also will include necessary steps regarding staff and participant debriefing in the case of an SAE related to research procedures.

For non-serious AEs that are anticipated, the study coordinator/principal investigator will submit a written periodic report to the NIDCD, IRB, and all participating investigators. Unanticipated, non-serious AEs will also be reported. The DSMB, in consultation with the study team, will determine the attribution category. The IRB will determine whether any modifications to the study protocol or consent forms are required.

Adverse event attribution categories:
1. Unrelated: The AE is clearly not related to the intervention
2. Unlikely: The AE is doubtfully related to the intervention
3. Possible: The AE may be related to the intervention
4. Probable: The AE is likely related to the intervention

5. Definite: The AE is clearly related to the intervention

If required, the study coordinator will revise the study protocol and consent forms as appropriate for approval by the IRB, and notice of IRB approval will sent to the NIDCD program officer and the DSMB.

Reporting of other study-safety events
As the study is being conducted, the PI will also inform NIDCD promptly of any changes in recruitment or in the protocol that are relevant to safety, as well as any actions taken by the IRB as a result of its continuing (annual or more frequent) review of the study. In the event of any major changes in the status of an ongoing protocol, the PI will inform the NIDCD immediately. Such changes would include:
• Amendments to the protocol
• Temporary suspension of participant accrual, or of the protocol
• Any change in informed consent or IRB approval status
• Termination of participant accrual, or of the protocol
• Other problems or issues that could affect the human subjects in the study

Data confidentiality, protection, and monitoring
All activities concerning data and human subjects protection will be approved by the University of Kentucky
IRB with the following requirements:
1. All participants must understand, agree to, and sign a consent form before participating.
2. Strict adherence to a participant's right to withdraw or refuse to answer questions is maintained.
3. The interviews and questionnaires are completely confidential and no names will be associated with the interviews or intervention activities. In all instances, the data files do not contain the name of the participant. Instead, each participant is assigned a unique four-digit identifying number.
4. Data will be secured. A computer file linking the unique number with the participant's name will be kept in the PI's office and hard copies of documents will be stored in locked file cabinets, separating identifiers from interview/questionnaire responses. All computer data will be stored on secure servers with access limited to approved CITI-trained study personnel.
5. At no time will a person who is not study staff be permitted to review identifying data.
6. All identifying information will be kept locked at all times, including during transportation between the study site and the PI's office via lockboxes.
7. All documentation of IRB approval, original consents, human participants certification for staff, and other related study information will be filed and easily accessible to the PI.
8. All study personnel must successfully complete IRB-approved training in human subjects protection.

Back to Top

Future Use and Sharing of Material (e.g., Data/Specimens/Information)

If the material collected for this study will be used by members of the research team or shared with other researchers for future studies, please address the following:

- list the biological specimens and/or information that will be kept
- briefly describe the types, categories and/or purposes of the future research
- describe any risks of the additional use
- describe privacy/confidentiality protections that will be put into place
- describe the period of time specimens/information may be used
- describe procedures for sharing specimens/information with secondary researchers
- describe the process for, and limitations to, withdrawal of specimens/data

Information collected in this study will not be used or shared for future research.

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short form use for incidentally encountered non-English subjects)
○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.
When recruiting Non-English-speaking subjects, provide a consent document in the subject's primary language. After saving this section, attach both the English and translated consent documents in the "Informed Consent" section.

Cultural and Language Consultants:

The PI is required to identify someone who is willing to serve as the cultural consultant to the IRB.

- This person should be familiar with the culture of the subject population and/or be able to verify that translated documents are

the equivalent of the English version of documents submitted.
- The consultant should not be involved with the study or have any interest in its IRB approval.
- Please include the name, address, telephone number, and email of the person who agrees to be the cultural consultant for your study.
- ORI staff will facilitate the review process with your consultant. Please do not ask them to review your protocol separately.

For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

Local Requirements:

If you will conduct research at an international location, identify and describe:

- relevant local regulations
- data privacy regulations
- applicable laws
- ethics review requirements for human subject protection

Please provide links or sources where possible. If the project has been or will be reviewed by a local ethics review board, attach a copy in the “Additional Information/Materials” section. You may also consult the current edition of the International Compilation of Human Research Standards

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?
○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [PDF], and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Initiated FDA-Regulated Research

Is this an investigator-initiated study that:

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?
○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the investigator assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [PDF], IDE regulatory requirements for SR device trials [PDF], and abbreviated regulatory requirements for NSR device trials [PDF]. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe the experience/knowledge/training (if any) of the investigator serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if any sponsor obligations have been transferred to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?
○ Yes ○ No
If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.
Attachments

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ◉ Yes ○ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

I have attached a HIPAA Waiver of Authorization. ◉ Yes ○ No

Attachments

Attach Type	File Name
Waiver	HIPAA WAIVER OF AUTHORIZATION_updated 1.10.22.pdf

STUDY DRUG INFORMATION

0 unresolved comment(s)

Drugs are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?

○ Yes ◉ No

If yes, complete the questions below. Additional study drug guidance.

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize Investigational Drug Service (IDS) pharmacies (Oncology or Non-Oncology). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ○ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Checkmark if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND) or if this is an Individual Patient Expanded Access IND (FDA Form 3926).

See FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs, and attach the following:

- FDA Form 3926;
- FDA expanded access approval or correspondence;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Expanded Access SOP.

Complete and attach the required Study Drug Form picking "Study Drug Form" for the document type. Any applicable drug documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.) should be attached using "Other Drug Documentation" for the document type.

Attachments

STUDY DEVICE INFORMATION

0 unresolved comment(s)

Medical devices are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals.

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

○ Yes ◉ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer “no” above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE) or Compassionate Use?

○ Yes ○ No

If Yes, complete the following:
IDE or HDE #(s)

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment IDE or Compassionate Use under the Food and Drug Administration (FDA) Expanded Access program.

For Individual or Small Group Expanded Access, see FDA's Early Expanded Access Program Information, and attach the following:

- FDA expanded access approval or sponsor’s authorization;
- An independent assessment from an uninvolved physician, if available;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Medical Device SOP.

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition [FDA's PDF] of Significant Risk (SR) device?

- Yes. Device(s) being tested in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- No. All devices being tested in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Complete and attach the required Study Device Form, picking the "Study Device Form" for the document type. Any applicable device documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.) should be attached using "Other Device Documentation" for the document type.

Attachments

RESEARCH SITES

0 unresolved comment(s)

To complete this section, ensure the responses are accurate then click "SAVE".

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☑ UK Classroom(s)/Lab(s)
- ☐ UK Clinics in Lexington
- ☐ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☐ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky (UK) or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page), including:

- A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.
- Supportive documentation, including letters of support, can be attached below. When attaching reliance documents, please ensure that you select the correct 'Document Type' from the drop-down menu. See below for the "**Document Types**" in bold, followed by examples of reliance documents for each type:
  - **Individual Investigator Agreement (IIA)**
    - A completed Individual Investigator Agreement

- IRB Approval (Non-UK)
- A Letter of Approval from a Non-UK IRB

- IRB Authorization Agreement (IAA)
- A SMART IRB Agreement
- An OHRP Agreement
- A DoD Agreement
- An IREx Reliance Notification
- Any Reliance Agreement

- Letter of Support & Local Context
- A Letter of Support from an organization at which some research activities are occurring
- Communications Plan
- Local Context Form

Please reach out to IRBReliance@uky.edu if you have any questions or concerns.

- NOTE: If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK sites.
- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

List all other non-UK owned/operated locations where the research will be conducted:

University of Colorado-Anschutz (Christina Studts as PI for the overall grant is faculty at CU effective 1/1/2020 - all human subjects activities will take place at UK and CU is relying on UK's IRB). University of Louisville (a subawardee of the study) will also assist with disseminating recruitment material, but all eligibility screening, enrollment, and data collection will occur with UK staff.

Describe the role of any non-UK site(s) or non-UK personnel who will be participating in your research.

Please describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites:

Attachments

Attach Type	File Name
-Individual Investigator Agreement	UKY IRB 45213_IIA_McWhirter.pdf
-Individual Investigator Agreement	UKY IRB 45213_IIA_Reiter.pdf
-Individual Investigator Agreement	Ryleigh Board IIA (UKY 45213).pdf
-Individual Investigator Agreement	UKY IRB 45213_IIA_Hails_Revised.pdf
-IRB Authorization Agreement	studts-creel IAA with UoL (UKY 45213).pdf
-IRB Authorization Agreement	Fully Executed SMART IRB IAA UCD-UK - FCU-DHH-45213.pdf
-IRB Authorization Agreement	Studts IAA between UK and KH&V (KH&V relying) (UKY 45213).pdf
-IRB Authorization Agreement	studts IAA CHFS.pdf
-Letter of Support & Local Context	UK.UCD.Studts.pdf
-Letter of Support & Local Context	UK Communication Plan Form between UK and UCDenver - Studts-Jacobs IAA 45213.pdf

B) If your research involves collaboration with any sites and/or personnel outside the University of Kentucky, then it is considered multisite research and IRB reliance issues will need to be addressed. This may include national multi-center trials as well local studies

involving sites/personnel external to UK. If you would like to request that the University of Kentucky IRB (UK IRB) serve as the lead IRB for your study, or if you would like the UK IRB to defer review to another IRB, please contact the IRBReliance@uky.edu.

RESEARCH ATTRIBUTES

0 unresolved comment(s)

Instructions: For various reasons, it is necessary to determine whether your research activities meet the definition of clinical research and/or a clinical trial. Your responses to the next series of questions will make that determination. For more details on the definitions, go to ORI's clinical research vs. clinical trial web page or visit NIH's decision tree for the NIH Clinical Trial definition.

Contact the Clinical Research Support Office (CRSO) if your study provides clinical services (e.g., labs, biopsies, tissue samples, physical exams, PT, counseling) regardless of payer (grant, federal, UK, industry)), utilizes UKHC space, or meets the NIH definition of a clinical trial (thereby requiring registry with CT.gov) as your study will need to be entered in OnCore to ensure appropriate regulatory tracking and billing. Visit CRSO FAQs for more information; requests for CCTS/CRSO services can be submitted via their service request form. For other questions, you can contact the CRSO Director, Jessica Heskel, at jhesk2@uky.edu.

My research activities include one or more of the following:

Patient-oriented research regarding mechanisms of human disease, therapeutic interventions, clinical studies, or development of new technologies
◉ Yes ○ No

Material of human origin (such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects
◉ Yes ○ No

Epidemiologic or Behavioral Studies
◉ Yes ○ No

Outcomes Research or Health Services Research
◉ Yes ○ No

Does your research study involve one or more human subjects prospectively assigned into one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes?
◉ Yes ○ No

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

☐ Academic Degree/Required Research
☐ Alcohol/Drug/Substance Abuse Research
☐ Biological Specimen Bank Creation (for sharing)
☐ Cancer Research
☐ CCTS-Center for Clinical & Translational Science
☑ Certificate of Confidentiality
☐ Collection of Biological Specimens for banking and use
☐ Community-Based Participatory Research
☐ Deception
☐ Educational/Student Records (e.g., GPA, test scores)
☐ Emergency Use (Single Patient)
☐ Gene Transfer

For additional requirements and information:

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality (look up "Confidentiality/Privacy...")
- CCTS (Center for Clinical and Translational Science)
- Clinical Research (look up "What is the definition of....)
- Clinical Trial
- Collection of Biological Specimens for Banking (look up "Banks, Repositories, Registries...")
- Collection of Biological Specimens (look up "Repositories, Registries, Specimen/Tissue Banks...")
- Community-Based Participatory Research (look up "Community-Engaged...")
- Data & Safety Monitoring Board (DSMB)

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

- ☐ Genetic Research
- ☐ NIH Genomic Data Sharing (GDS) (databases such as GWAS, dbGaP, GenBank)
- ☐ Treatment with Human Cells, Tissues, and Cellular and Tissue Based Products
- ☐ Individual Expanded Access or Compassionate Use
- ☐ International Research
- ☐ Planned Emergency Research Involving Exception from Informed Consent
- ☐ Recombinant DNA
- ☐ Registry or data repository creation
- ☐ Stem Cell Research
- ☐ Suicide Ideation or Behavior Research
- ☐ Survey Research
- ☐ Transplants
- ☐ Use, storage and disposal of radioactive material and radiation producing devices
- ☐ Vaccine Trials

*For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
- Genetic Research (look up "Banks, Repositories, ...Genetic/Genomic Data Sharing...")
- Gene Transfer

*For gene transfer research, also go to the E-IRB Application Other Review Committees section, and checkmark Institutional Biosafety Committee

- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Exception to Informed Consent*

*For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Use, storage and disposal of radioactive material and radiation producing devices

FUNDING/SUPPORT

0 unresolved comment(s)

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☐ Not applicable

Check All That Apply

- ☐ Grant application pending
- ☑ (HHS) Dept. of Health & Human Services
  - ☑ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Click applicable listing(s) for additional requirements and information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info-look up "Does the IRB Charge a Fee..."]
- National Science Foundation
- (DoEd) U.S. Department of Education
- (DoJ) Department of Justice or Bureau of Prisons
- (DoE) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist
- (EPA) Environmental Protection Agency

Other:

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

National Institute for Deafness and Other Communication Disorders

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.
If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

Attach Type	File Name
GrantContract	Research Strategy final.pdf

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP and DoD Summary for details)

○ Yes ◉ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

Assurance/Certification Attachments

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

○ Yes ◉ No

Additional Information

- ☐ Institutional Biosafety Committee
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- Institutional Biosafety Committee (IBC) - Attach required IBC materials
- Radiation Safety Committee (RSC) - For applicability, see instructions
- Radioactive Drug Research Committee (RDRC)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)** - Attach MCC PRMC materials, if any, per instructions.
- Office of Medical Education (OME)
- Graduate Medical Education Committee (GME)

Attachments

**** If your study involves cancer research, be sure to select "Cancer Research" in the "Research Attributes" section.** ORI will send your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRMC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

Do you want specific information inserted into your approval letter? ◉ Yes ○ No

Approval Letter Details:

If you wish to have specific language included in your approval letter (e.g., serial #, internal tracking identifier, etc…), type that language in the box below exactly as it should appear in the letter. The text you enter will automatically appear at the top of all approval letters, identical to how you typed it, until you update it. Don't include instructions or questions to ORI staff as those will appear in your approval letter. **If these details need to be changed for any reason, you are responsible for updating the content of this field.**

Aim 5 key stakeholder interviews - consent form, quantitative measures, qualitative interview guide

Additional Materials:

If you have other materials you would like to include for the IRB's consideration, check all that apply and attach the corresponding documents using the Attachments button below.

- ☐ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☐ Other Documents

Protocol/Other Attachments

Attach Type	File Name
Other	Fully Executed MOU Aim 2 UKPH CCSHCN V12P.pdf
Other	Fully executed MOU Aim 3 UKPH CCSHCN VI2P.pdf
Other	Safety Protocol - nationwide _ Jan 2023.pdf
Other	Safety Protocol - Kentucky _ Jan 2023.pdf
Other	IRB #45213 Permission to replace ICF.pdf

NOTE: [Instructions for Dept. of Health & Human Services (DHHS)-approved protocol]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

To view the materials currently attached to your application, click “All Attachments” on the left menu bar.

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

Introduction

All IRB applications require additional assurances by a Department Chairperson or equivalent (DA), and when applicable, a Faculty Advisor or equivalent (FA). This signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. The person assigned as DA *should not* also be listed in the Study Personnel section, and the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, refer to "What does the Department Chairperson's Assurance Statement on the IRB application mean?"

For a detailed illustration of how to complete this section, please review the short online video tutorial "Signatures (Assurance) Section - How to Complete." Otherwise, follow the steps below.

Required Signatures:

Individuals chosen as signees may remove the application from their Inbox without signing the Assurance Statement by clicking "Return to PI" with a comment about why it is being returned (e.g., specific edits are deemed necessary).

The PI, and personnel chosen as a contact, will receive an email notification that edits are needed, and can find the draft application in both the "Draft" folder and the "Signatures Status" folder located in the menu in the left margin of the default Inbox page. The researcher does not have a 'reply' option to the signee's comments and must make the requested edits directly in the application, or communicate outside the E-IRB system as to why not. Once the response is finalized, the researcher must re-visit the "Assurances Required" section to click the "Return to Signee" button for their re-consideration; the signee will receive an email notification at that time.

Hover your mouse cursor here for additional instructions.

First Name	Last Name	Role	Department	Signee Return Comment	Date Signed	
Raleigh	Jones	Department Authorization	Otolaryngology		03/02/2021 11:52 AM	View/Sign
Julie	Jacobs	Principal Investigator	Otolaryngology		12/11/2019 03:27 PM	View/Sign

Department Authorization

☑ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator has been notified of the additional regulatory requirements of the sponsor and by signing the principal investigator Assurance Statement, confirms he/she can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

**IF APPLICABLE FOR RELIANCE: I attest that the principal investigator has been notified of the regulatory requirements of both the Reviewing and Relying IRBs, according to the information provided in the E-IRB application. The attached Reliance Assurance Statement, signed by the principal investigator, confirms that he/she can comply with both sets of IRB requirements.

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☑ Furthermore, by checking this box, I also attest that:

- I have appropriate facilities and resources for conducting the study;
- I am aware of and take full responsibility for the accuracy of all materials submitted to the IRB for review;
- If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the categories specified in the Protocol Type: Exemption Categories section.
- If applying for an Abbreviated Application (AA) to rely on an external IRB, I understand that certain items above (1, 3, 4, 7-8) may not apply, or may be altered due to external institutional/IRB policies. I document my agreement with the Principal Investigator Reliance Assurance Statement by digitally signing this application.

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Once all Assurance Statement signatures have been acquired, return to this section to submit your application to ORI.

SUBMISSION INFORMATION

0 unresolved comment(s)

Each Section/Subsection in the menu on the left must have a checkmark beside it (except this Submission section) indicating the Section/Subsection has been completed. Otherwise your submission for IRB review and approval cannot be sent to the Office of Research Integrity/IRB.

If applicable, remember to update the Approval Letter Details text box under the Additional Information section

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and you will receive a message to notify you of the date.

If you are making a change to an attachment, you need to delete the attachment, upload a highlighted version that contains the changes (use Document Type of "Highlighted Changes"), and a version that contains the changes without any highlights (use the appropriate Document Type for the item(s)). Do **not** delete approved attachments that are still in use.

Your protocol has been submitted.

Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.074	smcgo0	9/19/2025 1:40:03 PM
	Stamped Consent Form	Aim 4 child assent (6yr+)_CLEAN 3.16.23.pdf		0.091	smcgo0	9/19/2025 1:40:02 PM
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	Stamped Consent Form	Aim 5_Parent interviews.pdf		0.477	smcgo0	9/19/2025 1:40:02 PM
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	-Individual Investigator Agreement	UKY IRB 45213_IIA_McWhirter.pdf	IIA Agreement - fully signed	0.229	ovmo223	2/14/2025 12:58:38 PM
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ResearchProcedures	Satisfaction with Interventionist (SIW) - includes TASCP.docx	Satisfaction with Interventionist (SIW) - includes TASCP	0.028	jja233	7/31/2024 6:26:10 PM
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DataCollection	GFTA.pdf		0.930	cbco233	5/21/2019 11:18:15 AM
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DataCollection	FCU Feedback Form -Rainbow Sheet.pdf		0.204	cbco233	5/21/2019 10:52:11 AM
DataCollection	MAIS.pdf		0.286	cbco233	5/21/2019 10:48:34 AM
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DataCollection	Semistructured interview guide for parents.docx		0.015	cbco233	5/21/2019 10:34:43 AM
GrantContract	Research Strategy final.pdf	NIH Research Strategy	0.870	jja233	7/26/2018 2:00:05 PM

	AddInfoProduct	Fully executed MOU Aim 3 UKPH CCSHCN VI2P.pdf	Aim 3 - fully executed MOU between UK and CCSHCN	0.211	jja233	6/14/2018 11:48:20 AM
	AddInfoProduct	Fully Executed MOU Aim 2 UKPH CCSHCN V12P.pdf	Aim 2 - fully executed MOU between UK and CCSHCN	0.039	jja233	6/14/2018 11:47:16 AM

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

NCT Number: NCT03916146

Statistical Analysis Plan

All tests will be two-sided with a 5% significance level and will be conducted in SAS. Analysis methods will account for clustering within parent coaches (i.e., statistical correlation among the outcomes from participants who share the same interventionist). Therefore, analysis of our primary outcome (parenting behaviors as measured by PARYC score at the first 6-month follow-up) will be achieved with linear mixed-effects modeling, with random effects to account for this clustering. A fixed effect for trial arm (FCU-DHH vs. TAU) will be the primary covariate of interest. Additional analyses will address each outcome over time (i.e., PARYC scores, PARCHISY scores, measures of child behavior, parent report and objective adherence with HA/CI, and language development). In longitudinal analyses, linear mixed effects modeling will be adjusted to account for the additional level of correlation among outcomes from the same subject (e.g., a random time effect or an unstructured covariance). Fixed effects will include trial arm, time (categorical or continuous variable), and their interaction, with the interaction being of primary interest. Because rolling study enrollment is necessary, some parent–child dyads may have fewer observations than others. Recommended statistical approaches will be used for missing data within interventionists (e.g., multiple imputation at the subject and cluster level). Sensitivity analyses will be considered and dictated by the type of missing data. We will measure potentially important predictors (e.g., sex, race, parental age, socioeconomic status, degree of hearing loss, type of hearing rehabilitation device, and baseline language development) and statistically compare the balance of the two trial arms. Secondary analyses will include these variables as covariates. Stratified randomization (by device type and poverty level) will be accounted for in analyses.

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