Document Coversheet

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

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	9/4/2024
NCT Number:	NCT03875339
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PROTOCOL TYPE (VERSION 4)

IRB Approval
9/4/2024
IRB # 47997
IRB3

IMPORTANT NOTE: You will not be able to change your selections for "Which IRB" and "Protocol Process Type" after having created your application. If you selected the wrong IRB or Protocol Process Type, you may need to create a new application. 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.

For guidance, see:

- Which IRB?
- 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.

EXPEDITED CERTIFICATION

0 unresolved comment(s)

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

A. Research activities that (1) present no more than *minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
B. The categories in this list apply regardless of the age of subjects, except as noted.
C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
D. The expedited review procedure may not be used for classified research involving human subjects.
E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

**"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. 45 CFR 46.102(i)*

Check the appropriate categories that apply to your research project:

☐ Study was originally approved by the full IRB at a convened meeting.

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

A. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
B. Research on medical devices for which (i) an investigational device exemption application is not required*; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

* Study must meet one of the IDE Exempt categories listed on the Device Form Attachment.
** An approved Device used in research according to its approved labeling is considered Exempt from IDE requirements.
NOTE: Select Category 1 for compassionate use medical device applications or individual patient expanded access investigational drug applications for which FDA has waived the requirement for full review.

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
B. From other adults and children* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

*In Kentucky, "child/children" refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Informed Consent SOP for discussion of "Emancipated Individuals" under Kentucky state law.) Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., DHHS, FDA, and U.S. Department of Education). Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." If conducting research outside the state of Kentucky, you are responsible for complying with applicable state law.

☐ 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

A. Hair and nail clippings in a nondisfiguring manner;
B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
C. Permanent teeth if routine patient care indicates a need for extraction;
D. Excreta and external secretions (including sweat);
E. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
F. placenta removed at delivery;
G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
J. Sputum collected after saline mist nebulization.

☑ 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
B. Weighing or testing sensory acuity;
C. Magnetic resonance imaging;
D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ 5) Research involving materials (data, documents, records, or specimens) that have been or will be collected solely for non-research purposes (such as medical treatment or diagnosis) as well as research involving existing information or specimens that were previously collected for research purposes, provided they were not collected for the currently proposed research. (Note: Some research in this category may qualify for Exempt review. This listing refers only to research that is not exempt.)
(Note: If submission includes materials previously collected for either non-research or research purposes in a protocol for which IRB approval expired, you may check Category 5. However, a separate category must also be selected for prospective collection of data/specimens obtained solely for research purposes)

☑ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☑ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

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.

Melissa Reedy-Johnson is being added as study staff because she has experience in community based research.

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

Communities Helping the Hearing of Infants by Reaching Parents: The CHHIRP Navigator trial

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.

CHHIRP Navigator Trial

Anticipated Ending Date of Research Project: 4/1/2025

Maximum number of human subjects (or records/specimens to be reviewed) 2300

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:	Matthew	Room# & Bldg:	740 South Limestone, E300E
Last Name:	Bush	Speed Sort#:	40536-0284
Middle Name	L		
Department:	Otolaryngology - 7H860	Dept Code:	7H860
PI's Employee/Student ID#:	00044987	Rank:	Associate Professor
PI's Telephone #:	859-218-2167	Degree:	MD, PhD, MBA
PI's e-mail address:	matthew.bush@uky.edu	PI's FAX Number:	8592575096
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	4/10/2023
		RCR Trained:	Yes

Do you, the PI, 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.

For Expedited and Exempt Applications, the research activities must be Risk Level 1 (no more than minimal risk to human subjects).

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.) 0 to 99

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 these resources:
NIH Diversity Policy
FDA Diversity Guidance

Specific Aim 1:

Based on our preliminary research, we anticipate enrolling 66% of all dyads, for a total of 1120 dyads. Once a clinic crosses from standard of care to PN in the stepped-wedge design, recruitment of all eligible parent-infant dyads in that clinic will begin. Prior to postnatal hospital discharge, parents whose infants fail their newborn hearing screening test are referred to university-based, private, or OCSHCN hearing centers for follow-up testing. The referral and contact information for these parents is collected and maintained by the state EHDI program. Within one week of postnatal hospital discharge, research personnel will contact by phone each parent referred to a OCSHCN clinic in the PN condition to describe the study, screen the parent-infant dyad for eligibility, and invite eligible dyads to enroll in the study. Informed consent will be obtained including permission to access infant hearing data from EHDI.

Inclusion criteria for parent-infant dyads:
1. Infant failed a hearing screening in one or both ears before postnatal hospital discharge
2. Infant was referred for follow-up diagnostic testing at one of the 10 participating CCSHCN clinics.
3. Parent able to speak English or another language using Cyracom, telephone interpreting service.

Exclusion criteria:
1. Children and parents live outside Kentucky or who will be moving out of Kentucky within the first three months of life.

Inclusion Criteria for Patient Navigators:
1. Age 21 years or older
2. Able to speak and read English
3. Willing to complete PN training and deliver PN.

Inclusion Criteria for Patient Navigators:
1. Age 18 years or older
2. Able to speak and read English
3. Employed at a participating OCSHCN clinic.

Specific Aim 2:

1) Patient Navigators: The PNs (N=30: 3 navigators per clinic) will be employed by the study and also enrolled as study participants. During the selection process, potential PNs will be informed by trained research staff of the purpose of the study and will provide written informed consent to participate in study procedures. We will attempt to employ a bi-lingual, Spanish-speaking navigator for each clinic area, but will also utilize Cyracom, telephone interpreting service that is ATA certified to reach any non-English speaking parent who may choose to participate in the study.

2) Clinic Administrators, Staff, and Providers: At each clinic, one administrator, one staff member, and one hearing healthcare provider (N=30) will be invited to participate in Aim 2. Inclusion criteria include: 1) age 18 years or older, and 2) able to speak and read English.

3) Parent Participants: All parent participants recruited in Aim 1 (N=1120) will also provide Aim 2 data during their baseline and post-test assessments. A subset of approximately 40 (depending on saturation) parent participants will be invited to also complete qualitative key informant interviews during their post-test assessment, after providing written informed consent. These parents will represent a combination of urban vs. rural communities and non-adherent vs. adherent results.

Aim 1 is involving the recruitment of 1120 parent-infant dyads over the course of 4 years referred for hearing testing to Office for Children with Special Health Care Needs (OCSHCN) clinics all across the state of Kentucky. The research will occur within 10 OCSHCN clinic offices across the state. This is a expansion of research conducted within this location approved under IRB protocol. These patients are referred to those clinics from birthing hospitals at the time of birth because the child fails a newborn hearing test in the newborn nursery. This is one while the child is in the hospital but usually no more than 3-4 weeks after the child is born. Once the dyad is referred to that OCSHCN clinic, the clinic schedules them for their office visit in that clinic. The OCSHCN staff (not any of our research personnel) ask the parent about being contacted by the research personnel and may insert a small flyer on the study that would accompany the appointment reminder if parent would like further information. If they agree to being contacted then the clinic staff send the name and contact number of the dyad to our research staff to contact about participation in the study. We do not cold call anyone and we do not go through any records to identify subjects. The potential participants are given to us by our partners at the OCSHCN. We then contact them by phone and go through the verbal consent over the phone. We do ask parents for additional contact methods, such as email or other contact, such as text messaging and make contact up to 5 times to participate if parent does not answer or requests return call initially. After one phone conversation, we may try to text the parent with general information to gauge further interest in participation. The text message would recall the research personnel he or she spoke to, a brief summary of the study and to contact research personnel if interested. The text would be sent only after initial contact to verify the parent phone number is correct. We will attach this form to OCSHCN referral form. We will not be going through any medical records at that OCSHCN clinic where there are going to be seen before, during, or after participation in the study. The participants provides any important medical information on the study questionnaire once informed consent is obtained. We do not have any physical contact with the proposed participants as they are likely many miles away and we do not have research personnel at the clinic. Doing the consent over the phone is the

only practice way to enroll these subjects into the study in a timely manner. It is critical to do this asap because we have to involve them in the research activities within the first week or 2 after birth. If we do this by mail we will not be able to conduct this research. We will not be going through any medical records.

Aim 2 involves selected interview with certain parents or clinic staff, etc. These will be in person when possible and written informed consent is obtained for this Aim. Informed consent with parents, patient navigators and clinic administrators and personnel can include in-person or via phone/Zoom. If the parent, patient navigator or clinic administrator/personnel is unable to access REDCap, the consent will be emailed to the participant with allowance of time to review informed consent form, ask questions, and sign and date and return back to the study team with by a secure email or fax machine only accessible to research personnel. If the consenting process occurs by phone or Zoom, the parents, patient navigators or clinic administrators/personnel will be sent a link via REDCap to review & sign the consent while on the phone/Zoom with study personnel. A copy of the consent will either be emailed to them automatically via REDCap if consented electronically or the copy of the signed consent will be mailed or emailed to the participants.

Attachments

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Census Regional Analyst Edition, 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:	6	15		
Black/African American:	58	134		
Latinx:	20	47		
Native Hawaiian/Pacific Islander:	0	0		
White:	598	1,422		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:	0	0		

If unknown, please explain why:

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

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:

☐ Prisoners ☑ Non-English Speaking (translated long or short form) ☐ International Citizens ☑ Normal Volunteers ☐ Military Personnel and/or DoD Civilian Employees ☑ Patients ☑ Appalachian Population	• UKMC Residents or House Officers [see requirement of GME] • 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:

This research studies an intervention which provides information and resources delivered over the phone to help families with infants to obtain timely medical evaluation after birth.

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.

Infants have hearing loss but many are delayed in diagnosis. The purpose of this study is to study patient navigation in this population and see if it helps children obtain timely diagnostic testing. It involves patient navigator intervention to support the parents. There are no harmful interventions conducted on children.

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?

Yes, patient navigation has been studied in adult populations and has been safe and effective to improve timely medical care.

C. Indicate how many children you propose to enroll in the study: 1120

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: This is based on the power calculation (see grant application)

D. Check all that apply:

- ☐ My research involves children 6 years of age or older.
- ☑ 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.
- ☐ 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.

N/A

G. Describe how parental permission will be obtained.

We will discuss the research protocol by phone and purpose of the study and have one parent sign the 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.

The research is conducted over the phone to parents and questionnaires sent to the family's home.

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.

The investigator has extensive research experience with vulnerable pediatric populations. The PI is a clinician who is an expert in pediatric hearing loss.

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.]:

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).

PREGNANT WOMEN/NEONATES/FETUSES

0 unresolved comment(s)

For studies involving pregnant women, human fetuses and/or neonates, check the option that best fits your research, then address the questions and requests for information.

☐ **Section 1: Research Involving Pregnant Women or Fetuses**

Research Involving Pregnant Women or Fetuses

A. Explain why the proposed research is scientifically appropriate, including descriptions of any pre-clinical studies on pregnant animals and any clinical studies on non-pregnant women that have been conducted and have provided data for assessing potential risks to pregnant women and fetuses.

B. Select the option that best describes the anticipated risk to the fetus:

○ Not greater than minimal; or
○ Greater than minimal risk and the risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.

C. Provide a rationale for anticipated risk:

D. Explain why any risk is the least possible for achieving the objectives of the research:

E. Select the options that apply:

○ Yes ○ No 1) This research holds out the prospect of direct benefit to the pregnant woman.

○ Yes ○ No 2) This research holds out the prospect of a direct benefit both to the pregnant woman and the fetus; or

○ Yes ○ No 3) This research does not hold out the prospect of direct benefit for the woman or the fetus, but the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

If "Yes" to any of these three questions, informed consent must be obtained from the pregnant woman or her legally authorized representative, but consent from the father is not required. The informed consent process should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus.

○ Yes ○ No 4) This research holds out the prospect of a direct benefit solely to the fetus.

If "Yes", informed consent must be obtained from the pregnant woman AND the father. The informed consent process should include a clear explanation regarding the reasonably foreseeable impact of the research on the fetus. NOTE: The father's informed consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity, or the pregnancy resulted from rape or incest.

○ Yes ○ No 5) This research will involve individuals under the age of 18 who are pregnant and are not considered emancipated minors.

If "Yes", assent from the pregnant child and permission from her parent or legal guardian must be obtained.

○ Yes ○ No 6) Will there be any inducements, monetary or otherwise, offered to terminate a pregnancy?

○ Yes ○ No 7) Will individuals performing research procedures have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy?

○ Yes ○ No 8) Will individuals performing research procedures have any part in determining the viability of a fetus?

☑ **Section 2. Research Involving Neonates**

Research Involving Neonates

A. Viable Neonates - A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accordance with the requirement of 45 CFR 46 Subpart A and Subpart D.

◉ Yes ○ No Does your research involve viable neonates?

If yes, you will need to complete the Children subsection before submitting this application (if the Children subsection is not visible, go to the "Subject Demographics" section, checkmark "Children", and save).

B. Neonates of Uncertain Viability AND Nonviable Neonates - Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by 45 CFR 46 Subpart B unless the IRB determines that certain conditions are met. Your responses to the following will help the IRB determine whether the conditions are met.

Explain why the proposed research is scientifically appropriate and provide a description of any pre-clinical and clinical studies that have been conducted which provide data for assessing potential risks to neonates.
If not applicable, please enter "N/A".

Research dependent upon abnormal newborn hearing screen

○ Yes ◉ No Will individuals engaged in the research have any part in determining the viability of a neonate?

C. Neonates of Uncertain Viability - Additional Requirements - Select the option that applies to your research.

☑ Not Applicable

○ The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, **AND** any risk is the least possible for achieving that objective.

○ The research has the main purpose of the development of important biomedical knowledge, which cannot be obtained by other means **AND** there will be no added risk to the neonate resulting from the research.

Explain the procedures that will be used to obtain legally effective informed consent of either parent of the neonate.

NOTE: If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative will be obtained. **These procedures must ensure that each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate. The father's informed consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.**

D. Nonviable Neonates – Additional Requirements - After delivery, a nonviable neonate may not be involved in research covered by 45 CFR 46 Subpart B unless the IRB determines that the following additional conditions are met.

☑ Not Applicable

○ Yes ○ No 1) Will the vital functions of the neonate be artificially maintained?

If "Yes", please explain:

Yes No 2) Does the research include procedures to terminate the heartbeat or respiration of the neonate?

Yes No 3) Will there be any added risk to the neonate resulting from this research?

If "Yes", please explain:

Yes No 4) Is the sole purpose of the research for the development of important biomedical knowledge that cannot be obtained by other means?

If "Yes", please explain:

5) Explain the procedures that will be used to obtain legally effective informed consent of both parents of the neonate.

Note: *If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice. The consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice.* ***These procedures must ensure that each individual providing informed consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate.***

☐ **Section 3. Research Involving After Delivery, The Placenta, The Dead Fetus, Or Fetal Material**

Research Involving After Delivery, The Placenta, The Dead Fetus, Or Fetal Material

A. This research proposes to use the following: (Check all that apply)

- ☐ Placenta
- ☐ The Dead Fetus
- ☐ Macerated Fetal Material
- ☐ Cells Excised from Dead Fetus
- ☐ Tissue Excised from Dead Fetus
- ☐ Organs Excised from Dead Fetus
- ☐ Other

If 'Other' Describe:

NOTE: The use of any of the above must be conducted in accordance with any applicable Federal, State, or local laws, regulations, and institutional policies regarding such activities.

B. Yes No Will any information associated with the material identified above be recorded for research purposes in such a manner that living individuals can be identified, directly or through identifiers linked to those individuals?

If "Yes", provide a rationale for the recording of identifiable information [Note: those individuals are considered to be research subjects and all pertinent human subject regulations are applicable to their participation.]:

☐ **Section 4. Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem**

Affecting the Health or Welfare of Pregnant Women, Human Fetuses, or Neonates

If the study is Department of Health and Human Services (HHS) funded, or funding by HHS is sought, review by the Secretary of HHS and posting in the Federal Register for public comments and review is required. If this category is applicable, the Office of Research Integrity will prepare and submit a report of IRB review to the appropriate HHS institutional official.

Select all that apply:

- ☐ Neonates
- ☐ Pregnant Women
- ☐ Fetal Material

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

- ☐ Informed Consent Form (and/or Parental Permission Form and/or translated short form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script
- ☐ 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

Informed Consent Process:

Using active voice, 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

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.

(See p. 146 and following of attached grant application)

a) Patient-level recruitment will involve all parents of infants who fail an infant hearing screening and are referred to an Office for Children with Special Health Care Needs (CCSHCN) clinic for outpatient audiological testing during the window in which that clinic is implementing the patient navigation (PN) intervention. Under a sequential rollout in steps of 6-month intervals, 10 OCSHCN clinics throughout Kentucky will be randomly allocated to cross from the control condition (standard of care) to the PN condition over the project period. (OCSHCN operates 11 total clinics geographically dispersed across the state; one clinic receives too few infant audiology referrals to be included in this study.) Randomization will be stratified by clinic patient population size. No randomization will occur at the individual level. By the study's end, all clinics will have participated in the PN intervention for a minimum of 1 year and a maximum of 4 years. We anticipate approximately 1700 failed newborn screening referrals to the 10 clinics during their time in the PN intervention condition (i.e., 50 six-month periods across all 10 clinics). Based on our preliminary research, we anticipate enrolling 66% of all dyads, for a total of 1120 dyads. This enrollment would reflect an average enrollment of 22.4 participants per clinic per six-month period of the intervention condition. Because collected data will pertain to both the infant and the parent, both will be considered research participants; thus, the total planned sample size is 2240. Study eligibility will be assessed via telephone by a member of the research team who is CITI-trained in human subjects protection, and parents will provide verbal consent for their participation and their child's participation in the study. Approximately 40 already-enrolled parents will also participate in key informant qualitative interviews after a separate informed consent process. No additional inclusion/exclusion criteria will apply. At no time during this study will prospective dyads be selected by examining medical records. Dyads will be referred by the various OCSHCN clinics, and not contacted by study personnel until that time. Additionally, no survey results, or interview information (if applicable), will be added to patient records and will only be held by research personnel for the time period required by the IRB before they are destroyed.

b) Patient navigators will be identified in collaboration with our Community Advisory board, stakeholders from the OCSHCN, and leadership for the Kentucky Chapter of Hands & Voices. We will also recruit navigators from an existing pool of parents/patients who have requested to be involved in hearing healthcare research and patient advocacy maintained by Kentucky's OCSHCN. Three navigators will be needed at each of the 10 clinics (n=30). At least one bilingual (Spanish-English) navigator will attempted to be recruited for each site, but we will also utilize Cyracom, an ATA certified interpretation service to contact parents throughout the research procedures. In the case of turnover, new PNs will be identified and trained.

c) Lastly, one clinic administrator, one staff member, and one hearing healthcare provider from each of the OCSHCN clinics (n=30) will be recruited to participate in key informant interviews and to complete quantitative measures related to Aim 2.

As described above, staff at the OCSHCN will identify all infant referrals to a clinic in the intervention period and provide parent contact information to the UK research team. A CITI-trained interviewer with experience in recruiting and enrolling participants in human subjects research will describe the study, screen the parent-child dyad for eligibility, and invite eligible dyads to enroll in the study. Verbal informed consent for study participation will be obtained at that time from the parent of the eligible child on behalf of the parent and of the child. The infant will not be able to provide assent. This study will require a waiver of documentation of informed consent, as it is not feasible to obtain the written consent of all participants due to the large number and distance between OCSHCN clinics and the University of Kentucky.

Appropriate measures and care will be taken in the recruitment of research participants from vulnerable populations. Regarding the recruitment of parent participants under 18 years of age and their infant children, the participant may give consent for services for her/his child and herself/himself without the consent of the participant's parent or legal representative (according to KRS 214.145). We will also recruit infants who are wards of the state by contacting the local Department for Community Based Services (DCBS) Social Services Worker (SSW) or supervisor. The SSW or supervisor will determine the type of custody designation the child has been assigned and identify an advocate for the infant in addition to any other individual acting on behalf of the child as guardian or in

loco parentis. Informed consent will be obtained from the advocate and the guardian of the infant, as mandated by the DCBS.

All participants will be individually informed about the study aims and procedures. The following areas will be explained in detail: why they are being invited to participate, who is conducting the research, the purpose of the study, inclusion and exclusion criteria, study location, time commitment, what they will be asked to do, permission to access the infant's hearing data from the Early Hearing Detection and Intervention database, risks and benefits in participating, the voluntary nature of the study, costs participation may incur, confidentiality, their right to end participation early, payment for participation, and contact information of the PI and Office of Research Integrity for any questions, suggestions, concerns, or complaints. The research staff conducting the consent interview will record that they have obtained verbal consent from the participant and the date on which it occurred. A separate consent process will occur for parents who agree to participate in qualitative interviews, covering the same areas of detail. Written consent will be obtained in this case immediately preceding the interview.

Written informed consent will be required for parents participating in qualitative interviews, for PNs (for their participation in baseline and post-test research measures), and for clinic administrators, staff, and providers. For Aim 2, Informed consent with parents, patient navigators and clinic administrators and personnel can include in-person or via phone/Zoom. If the parent, patient navigator or clinic administrator/personnel is unable to access REDCap, the consent will be emailed to the participant with allowance of time to review informed consent form, ask questions, and sign and date and return back to the study team with by a secure email or fax machine only accessible to research personnel. If the consenting process occurs by phone or Zoom, the parents, patient navigators or clinic administrators/personnel will be sent a link via REDCap to review & sign the consent while on the phone/Zoom with study personnel.

When using the REDCap e-consent function, a member of the study team will connect with the potential participant either through phone or Zoom, depending on the participant's capabilities. This will allow for a member of the study team to go over the consent with the participant and answer any questions he or she may have during the consent process. While on the phone or via Zoom with the potential participant, the authorized study team member obtaining consent will go into the study's REDCap form designated for the participant arm and add a new record. Once the study team member has added a new record, he or she will complete the Recruiter data collection instrument. The study team member will put his or her first and last name in the designated boxes as well as put the potential study participant's email in the designated field as shown below. To automatically send the Consent link to the participant, the study team member will check Yes to the "Send consent email to participant" question. Once all of the four fields have been filled out, the study team member will mark the form as complete. Once this Recruiter from is marked as complete, the email containing the link to the e-consent in REDCap will automatically send to participants. The participant will then click on the link to complete the e-consent. Pages of the stamped version of the consent will display in chronological order. At the end, the participant will have to answer two questions. The first one being whether or not they consent to the study. The second question asks if the research team can contact them about future studies. Once the participant marks he or her answers, They have to use the signature function to sign their name. The participant will also have to select the date. Please note that the name of the authorized person obtaining consent is located before the Next Page button. This name is pulled using REDCap piping logic from the Recruiter form that is filled out initially by the study team member. Once the participant fills out all of the questions, he or she will then click Next Page. The next page is the e-consent certification page that is built into REDCap. This provides the participants a way to certify that the information they entered is correct and that by electronically signing this is equivalent to them signing a paper consent form. If everything looks correct, the participant will check the small box in the yellow box and click Submit. After they click Submit, a copy of the signed consent form is automatically sent to their email. Participants can click on the link to view & download the signed, certified consent form. Additionally, the PDF of the signed copy of the consent is also saved in REDCap under the File Repository function so that the study team can access them at any time. A study team member will review the signed consent to make sure everything looks correct. (Please see the REDCap e-consent instructions PDF located in the Additional Information/Materials section of the e-IRB application)

Whether in person or via phone/Zoom, a CITI-trained interviewer will provide a written copy of a consent document written in a basic language and will also verbally review the following: why they are being invited to participate, who is conducting the research, the purpose of the study, inclusion and exclusion criteria, study location, time commitment, what they will be asked to do, risks and benefits in participating, the voluntary nature of the study, costs participation may incur, confidentiality, their right to end participation early, payment for participation, and contact information of the PI and Office of Research Integrity for any questions, suggestions, concerns, or complaints. A copy of the signed informed consent document will be provided to the participant either in-person or via email if using the REDCap function. In the case of a non-English speaking parent, a short-form translation of the informed consent form will be provided by Cyracom in the parents' preferred language and a translation certificate and attestation will accompany the consent to provide to parent and file in the locked research office.

Aim 1 is involving the recruitment of 1120 parent-infant dyads over the course of 4 years referred for hearing testing to Office for Children with Special Health Care Needs (OCSHCN) clinics all across the state of Kentucky. These patients are referred to those clinics from birthing hospitals at the time of birth because the child fails a newborn hearing test in the newborn nursery. This is one while the child is in the hospital but usually no more than 3-4 weeks after the child is born. Once the dyad is referred to that OCSHCN clinic, the clinic schedules them for their office visit in that clinic. The OCSHCN staff (not any of our research personnel) ask the parent about being contacted by the research personnel and may insert a small flyer on the study that would accompany the appointment reminder if parent would like further information. If they agree to being contacted then the OCSHCN staff send the name and contact number of the dyad to our research staff to contact about participation in the study. We do not cold call anyone and we do not go through any records to identify subjects. The potential participants are given to us by our partners at the OCSHCN. We then contact them by phone and go through the verbal consent over the phone. We do ask parents for additional contact methods, such as email or other contact, such as text messaging and make contact up to 5 times to participate if parent does not answer or requests return call initially. After one phone conversation, we may try to text the parent with general information to gauge further interest in participation. The text message would recall the research personnel he or she spoke to, a brief summary of the study and to contact research personnel if interested. The text would be sent only after initial contact to verify the parent phone number is correct. We will attach this form to initial OCSHCN referral form. We will not be going through any medical records at that OCSHCN clinic where there

are going to be seen before, during, or after participation in the study. The participants provides any important medical information on the study questionnaire once informed consent is obtained. We do not have any physical contact with the proposed participants as they are likely many miles away and we do not have research personnel at the clinic. Doing the consent over the phone is the only practice way to enroll these subjects into the study in a timely manner. It is critical to do this asap because we have to involve them in the research activities within the first week or 2 after birth. If we do this by mail we will not be able to conduct this research. We will not be going through any medical records.

Aim 2 involves selected interview with certain parents or clinic staff, etc. These will be in person when possible and written informed consent is obtained for this Aim. Informed consent with parents, patient navigators and clinic administrators and personnel can include in-person or via phone/Zoom. If the parent, patient navigator or clinic administrator/personnel is unable to access REDCap, the consent will be emailed to the participant with allowance of time to review informed consent form, ask questions, and sign and date and return back to the study team with by a secure email or fax machine only accessible to research personnel. If the consenting process occurs by phone or Zoom, the parents, patient navigators or clinic administrators/personnel will be sent a link via REDCap to review & sign the consent while on the phone/Zoom with study personnel. A copy of the consent will either be emailed to them automatically via REDCap if consented electronically or the copy of the signed consent will be mailed or emailed to the participants.

The research will occur within 10 OCSHCN clinic offices across the state. This is a expansion of research conducted within this location approved under IRB protocol.
The Principal Investigator, Matthew L. Bush, M.D. will be responsible for monitoring the safety of the subjects involved. The PI will provide a summary of the DSM report to NIH on an annual basis as part of the progress report. The DSM report will include the subjects' sociodemographic characteristics, expected versus actual recruitment rates, retention rates, any quality assurance or regulatory issues that occurred during the past year, summary of adverse events (AEs) and serious adverse events (SAEs) and any actions or changes with respect to the protocol. We will make every effort to keep private all research records. The questionnaires, informed consents, and any other study documents will be kept in the locked office of the PI at the University of Kentucky. The same office will contain a password-protected computer that will house electronic data of the subjects. Subject that experience an adverse event or emotional distress will be instructed to call Matthew L. Bush, M.D. at 859-257-5097 immediately. Further questions, suggestions, concerns, or complaints about the study, can be addressed by the staff in the Office of Research Integrity at the University of Kentucky at 859- 257-9428 or toll free at 1-866-400-9428.

Update 2/23/24: Enrollment for this study has ended, so consent documents were removed from this section of the protocol.

☐ 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.

e) If the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

- Private information/specimens are "identifiable" if the investigator may ascertain the identity of the subject or if identifiers are associated with the information (e.g., medical records). This could be any of the 18 HIPAA identifiers including dates of service.
- If not using identifiable private information or identifiable biospecimens, insert N/A below.

☑ 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:

This research studies an intervention which provides information and resources delivered over the phone to help families with infants to obtain timely medical evaluation after birth.
Aim 1 is involving the recruitment of 1120 parent-infant dyads over the course of 4 years referred for hearing testing to Office for Children with Special Health Care Needs (OCSHCN) clinics all across the state of Kentucky. These patients are referred to those clinics from birthing hospitals at the time of birth because the child fails a newborn hearing test in the newborn nursery. This is one while the child is in the hospital but usually no more than 3-4 weeks after the child is born. Once the dyad is referred to that OCSHCN clinic, the clinic schedules them for their office visit in that OCSHCN clinic. The clinic staff (not any of our research personnel) ask the parent about being contacted by the research personnel and may insert a small flyer on the study that would accompany the appointment reminder if parent would like further information. If they agree to being contacted then the OCSHCN clinic staff send the name and contact number of the dyad to our research staff to contact about participation in the study. We don't cold call anyone and we don't go through any records to identify subjects. The potential participants are given to us by our partners at the OCSHCN. We then contact them by phone and go through the verbal consent over the phone. We will not be going through any medical records at that OCSHCN clinic where there are going to be seen before, during, or after participation in the study. The participants provides any important medical information on the study questionnaire once informed consent is obtained. We do not have any physical contact with the proposed participants as they are likely many miles away and we do not have research personnel at the clinic. Doing the consent over the phone is the only practice way to enroll these subjects into the study in a timely manner. It is critical to do this asap because we have to involve them in the research activities within the first week or 2 after birth. If we do this by mail we will not be able to conduct this research. We will not be going through any medical records.

Aim 2 involves selected interview with certain parents or clinic staff, etc. These will be in person when possible and written informed consent is obtained for this Aim. Informed consent with patient navigators and clinic administrators and personnel can include in-person and emailed consent with allowance of time to review informed consent form, ask questions, and sign and date to either give to research personnel or email or fax back to personnel.

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):

Hearing testing of infants after a failed newborn hearing screening is performed whether or not the subjects are enrolled in the study. The study involves over 1120 all over the state of Kentucky and the timing of enrolling them and providing the phone intervention must occur prior to their scheduled testing. This must be performed typically within 1-

2 weeks after birth and the study is time-sensitive. The only feasible way to enroll these subject would be through phone consent and thus we request a waiver of documentation of informed consent.

Aim 1 is involving the recruitment of 1120 parent-infant dyads over the course of 4 years referred for hearing testing to OCSHCN clinics all across the state of Kentucky. These patients are referred to those clinics from birthing hospitals at the time of birth because the child fails a newborn hearing test in the newborn nursery. This is one while the child is in the hospital but usually no more than 3-4 weeks after the child is born. Once the dyad is referred to that OCSHCN clinic, the clinic schedules them for their office visit in that clinic. The OCSHCN staff (not any of our research personnel) ask the parent about being contacted by the research personnel and may insert a small flyer on the study that would accompany the appointment reminder if parent would like further information. If they agree to being contacted then the OCSHCN staff send the name and contact number of the dyad to our research staff to contact about participation in the study. We don't cold call anyone and we don't go through any records to identify subjects. The potential participants are given to us by our partners at OCSHCN. We then contact them by phone and go through the verbal consent over the phone. We will not be going through any medical records at that clinic where there are going to be seen before, during, or after participation in the study. The participants provides any important medical information on the study questionnaire once informed consent is obtained. We do not have any physical contact with the proposed participants as they are likely many miles away and we do not have research personnel at the clinic. Doing the consent over the phone is the only practice way to enroll these subjects into the study in a timely manner. It is critical to do this asap because we have to involve them in the research activities within the first week or 2 after birth. If we do this by mail we will not be able to conduct this research. We will not be going through any medical records.

Aim 2 involves selected interview with certain parents or clinic staff, etc. These will be in person when possible and written informed consent is obtained for this Aim. Informed consent with patient navigators and clinic administrators and personnel can include in-person and emailed consent with allowance of time to review informed consent form, ask questions, and sign and date to either give to research personnel or email or fax back to personnel.

○ **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 Getting Started 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
Bellnier	Laura	Study Coordinator	DP	Y	Y	MPH	P	Y	07/08/2022	Y	N	03/23/2023	N	Y
Byers	Sara	Data Analysis/Processing	SP	N	N		N	Y	03/03/3000		N	02/28/2024	N	Y
Creel	Liza	Co-Investigator	SP	Y	N	PhD	N	Y	03/03/3000		N	06/28/2019	N	Y
Danby	Margaux	Project Assistance/Support	SP	N	N		S	Y	07/05/2022	Y	N	10/07/2021	N	Y
Ekman	Matthew	Project Assistance/Support	SP	N	N		P	Y	03/15/2022		N	10/07/2021	N	N
Fields	Madilyn	Project Assistance/Support	SP	Y	N		P	Y	08/31/2023	Y	N	05/04/2023	N	Y
Jacobs	Julie	Consultant/Advisor	SP	N	N	MPH	P	Y	05/07/2024	Y	N	11/14/2019	N	Y
Mahairas	Anthony	Study Coordinator	SP	Y	Y	BS	P	Y	09/13/2021	Y	N	09/13/2021	N	Y
Reedy-Johnson	Melissa	Project Assistance/Support	DP	Y	N		P	Y	09/23/2022	Y	N	09/04/2024	N	Y
Schoenberg	Nancy	Co-Investigator	SP	Y	N	PhD	P	Y	03/04/2024	Y	N	07/27/2020	N	Y
Shinn	Jennifer	Co-Investigator	DP	Y	N	PhD	P	Y	03/13/2023	Y	N	07/27/2020	N	Y
Stringer	Paul	Study Coordinator	DP	Y	Y		P	Y	05/08/2023	Y	N	05/11/2023	N	Y
Studts	Christina	Co-Investigator	SP	Y	N	PhD	N	Y	03/03/3000		N	02/26/2024	N	Y
Taylor	Olivia	Project Assistance/Support	SP	N	N		S	Y	01/07/2022		N	01/07/2022	N	Y
Travis	Lori	Consultant/Advisor	SP	Y	N	Au. D.	N	Y	03/03/3000		N	07/24/2019	N	Y
Westgate	Philip	Co-Investigator	SP	Y	N	PhD	P	Y	05/25/2023	Y	N	07/27/2020	N	Y
Balasuriya	Beverly	Project Assistance/Support	SP	N	N	MS	P	N	07/15/2019		Y	02/23/2024	N	Y
Board	Ryleigh	Study Coordinator	SP	Y	N		P	Y	06/09/2022		Y	02/23/2024	N	N
Board	Ryleigh	Project Assistance/Support	SP	Y	N		N	Y	03/03/3000		Y	02/23/2024	N	Y
Dyer	Kris	Study Coordinator	DP	N	N	BS	P	Y	06/10/2024	Y	Y	01/06/2020	N	Y
Hatfield	Miranda	Study Coordinator	DP	Y	N	MSW	P	N	08/16/2021	N	Y	05/04/2023	N	Y
Perez	Nicole	Project Assistance/Support	SP	N	N	BS	P	N	12/31/2020	N	Y	02/23/2024	N	Y
Rankin	Rashondra	Project Assistance/Support	SP	Y	N		P	Y	06/01/2023	Y	Y	02/23/2024	N	Y
Ranseen	Emily	Project Assistance/Support	SP	N	N		P	Y	12/18/2023	N	Y	05/11/2023	N	Y
Rush	Elizabeth	Study Coordinator	DP	Y	N	BA	P	N	02/18/2020		Y	05/04/2023	N	N
Schuh	Marissa	Study Coordinator	DP	Y	N	BS	P	Y	09/21/2022		Y	05/04/2023	N	Y

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Studts	Christina	Co-Investigator	DP	Y	N	PhD	N	Y	03/03/3000		Y	02/26/2024	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).

As the most common neonatal sensory disorder, infant hearing loss has an incidence of at least 1.7 per 1000 births. Early childhood hearing loss that is not identified and treated appropriately typically results in significant delays in language, cognitive, and social development, with profound later effects on education and employment. The economic costs of hearing loss are substantial: the overall lifetime medical, educational, and occupational costs due to deafness are estimated to be $2.1 billion.4 The U.S. Preventive Services Task Force (USPSTF) reported that early detection and intervention of infant hearing loss decreases speech impairment, social/emotional challenges, and learning/behavioral disorders.5-7 The Joint Committee on Infant Hearing (JCIH) recommends that all infants be screened before 1 month of age, diagnosed before 3 months of age, and initiate treatment before 6 months of age (often referred to as the "1-3-6 rule"). Early infant hearing detection and intervention (EHDI) programs are coordinated on a state level and infant hearing healthcare is typically delivered in community clinics or health departments; however, non-adherence to diagnostic testing after failed newborn screening is a national problem. EHDI programs aim to have 90% of U.S. infants with failed infant hearing screens tested and diagnosed within 3 months of failed screening, but fall unacceptably short: only 40.6% meet that standard. Heightening the concern for life-long complications due to delayed diagnosis following a failed newborn screening, the outpatient diagnostic and hearing loss treatment process is complex and difficult for parents to navigate. Families of children with hearing loss are often uninformed regarding the EHDI process and lack peer support in obtaining care for their child. Similar problems in cancer care have been addressed with patient navigation (PN) programs, leading to improved adherence to recommended diagnostic testing after abnormal screening, improved patient care, and healthcare system cost savings. Patient navigators (PNs) are trained individuals who assess and mitigate personal/environmental barriers to promote healthcare adherence and improve access to care. Our recent randomized controlled trial performed in an academic setting demonstrated PN efficacy in infant hearing healthcare. This study, conducted in collaboration with the Kentucky EHDI program, demonstrated that PN decreased infant hearing testing non-adherence (7%) compared to the standard of care (38%; p=0.005). Our next step is to examine the effectiveness of PN when delivered in the diverse communities served by state EHDI systems. Guided by our Community Advisory Board (CAB), EHDI partners, and hearing healthcare stakeholders, we will conduct a type 1 hybrid effectiveness-implementation trial in 10 state-funded community hearing healthcare clinics, testing PN while simultaneously investigating implementation outcomes, factors influencing implementation, and cost-effectiveness.

To summarize the current recommendations, infants are to be screened for hearing loss in the hospital of birth prior to discharge using electrophysiologic tests. If one or both ears fail the testing, an audiologist then performs a complete diagnostic evaluation. A diagnosis of hearing loss should be made before 3 months of age and intervention with amplification should occur prior to 6 months of age. In the event of poor rehabilitation with amplification and continued failed testing, the patient should undergo cochlear implantation by 12 months of age. The benefit of early identification is that timely intervention can improve language and speech acquisition in hearing-impaired children. Our research group has assessed the age of diagnosis and age of appropriate intervention in children with hearing loss in Kentucky. We have identified a statistically significant delay in diagnosis and treatment for patients from the Appalachian region of Kentucky, and, as a result of this discovery, are examining the causative factors behind this delay. The lack of education and family support is a common theme in families that fail to follow-up or delay their follow-up significantly. We are proposing a study to examine the effect of a patient navigator to influence patient satisfaction, patient/family behavior and the age of diagnosis of pediatric hearing loss

Objectives

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

(See grant application p. 128)

Hypothesis: PN will decrease non-adherence to obtaining infant hearing diagnosis within 3 months after birth compared to the standard of care.

Specific Aim 1: Using a stepped-wedge randomized trial design, we will test the effectiveness of PN to decrease non-adherence to receipt of infant hearing diagnosis within 3 months after birth. Delivery of PN in each community will be informed by feedback from the CAB and community stakeholders.

Specific Aim 2: Aim 2 will investigate factors associated with implementation and effectiveness outcomes across the 10 clinic sites. This aim is guided by the Consolidated Framework for Implementation Research (CFIR), using implementation constructs and outcomes recommended by Proctor et al. Sources of data for this aim will include process records as well as quantitative and qualitative data from PNs; clinic administrators, staff, and providers; and parent participants. Consistent with CFIR, we will assess PN knowledge and behaviors following completion of the PN curriculum, including intervention fidelity; PN characteristics; inner and outer setting clinic characteristics; and four key implementation outcomes: adoption, recruitment/retention, reach/penetration, and sustainability.

Specific Aim 3: Aim 3 involves incremental cost-effectiveness analyses in which net costs and net effectiveness of the intervention will be compared with that of standard of care for patients referred to OCSHCN clinics after a failed newborn hearing screen. Hypothesis: (a) PN after a failed newborn hearing screen will be cost effective compared to the standard of care from the perspective of third-party payers. We will compare net costs and effectiveness of PN compared to standard of care. Results will be expressed as a ratio of differences in observed costs to differences of observed outcomes. The perspective of this evaluation will be third party payers.

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.

(See p.133 and following of attached grant submission)

For Specific Aim 1:
We will (1) use a stepped-wedge trial design to deliver patient navigation (PN) sequentially in 10 state-funded Kentucky Office for Children with Special Healthcare Needs (OCSHCN) clinics randomized to cross from usual care to PN in steps of 6-month intervals over the project period. Prior to initiation of PN at each clinic, the control condition will be the standard of care. The overall effectiveness of PN will be tested by comparing non-adherence rates during the PN condition to those during the standard of care condition. Simultaneously, we will (2) assess preliminary implementation outcomes (i.e., acceptability, adoption, recruitment/retention, and fidelity) as well as multilevel factors influencing implementation of PN in each clinic. The research will occur within 10 OCSHCN clinic offices across the state. This is a expansion of research conducted within this location approved under IRB protocol."

For Specific Aim 2:

Patient Navigators: Baseline data collection from PNs will occur immediately following study enrollment and before PN training, administered by a trained interviewer. At the conclusion of PN training, PNs will take an examination to ensure comprehension of critical principles necessary for successful navigation. A score >80% will be required to pass the training. PNs with less than a passing score will be allowed to repeat relevant training elements and retake the examination one time; if the examination is not passed on the second round, the PN will no longer be employed in this study and a new PN will be identified. For those who pass the examination and proceed to intervention delivery, PNs will (1) audio-record 10% of PN sessions (with parent permission) to allow assessment of fidelity, (2) complete a PN fidelity checklist following each PN session (6 total checklists), and (3) maintain process logs detailing time, travel, attendance, frequency and modes of contact with families, and other activities and expenses associated with PN delivery. Approximately 6 months after completing PN training, PNs will complete post-test assessments and key informant interviews, administered by a trained interviewer. PNs will be compensated $25 at baseline and post-test for completing the battery of assessments. In each clinic, PN will continue after the 6-month assessment time point until the end of the 2nd quarter of Y5. These data will be shared with the CAB quarterly and recommendations on additional PN training or PN modifications will be observed.

Clinic Administrators, Staff, and Providers: Approximately 6 months after crossing to the PN condition, administrators, staff, and providers from each clinic will participate in key informant interviews and complete quantitative measures administered by a trained interviewer.

Parent Participants: At the Aim 1 post-test assessment (16 weeks post-birth), parents will complete a PN satisfaction measure and questionnaires. Selected parents (N~40) will also complete a 1-hour semi-structured key informant interview exploring parents' experiences with the PN intervention.

For Specific Aim 3:

Both direct and indirect costs associated with PN will be included. Costs associated with the initial newborn hearing screen will be excluded from analyses since these costs are incurred for all infants regardless of outcomes.
Direct costs include the cost of: PN establishment (PN recruitment and training costs), program implementation (office space, PN time, PN travel and tools, PN materials, PN supervision, staff turnover), parent time and travel (travel to seek diagnostic or PN services, time

spent receiving diagnostic services), treatment costs (costs of a rescreen or diagnostic audiology appointment), nonmedical costs (potential cost savings due to earlier identification), and non-adherence costs for the clinics (no-show appointments). Research activity costs (e.g., data collection, human subject protection training of PNs) are not included.
Indirect costs include opportunity costs of time (e.g. loss of productivity/wages) for the parent(s).

Effectiveness: The measured outcome of effectiveness to which costs will be compared is the proportion of individuals in each group who achieve diagnosis by 3 months of age. We will derive these outcome data using clinic-level non-adherence rates reported monthly by EHDI, collected in Aim 1.

Aim 1 is involving the recruitment of 1120 parent-infant dyads over the course of 4 years referred for hearing testing to OCSHCN clinics all across the state of Kentucky. The research will occur within 10 OCSHCN clinic offices across the state. This is a expansion of research conducted within this location approved under IRB protocol. These patients are referred to those clinics from birthing hospitals at the time of birth because the child fails a newborn hearing test in the newborn nursery. This is one while the child is in the hospital but usually no more than 3-4 weeks after the child is born. Once the dyad is referred to that OCSHCN clinic, the clinic schedules them for their office visit in that clinic. The OCSHCN staff (not any of our research personnel) ask the parent about being contacted by the research personnel and may insert a small flyer on the study that would accompany the appointment reminder if parent would like further information. If they agree to being contacted then the OCSHCN staff send the name and contact number of the dyad to our research staff to contact about participation in the study. We do not cold call anyone and we do not go through any records to identify subjects. The potential participants are given to us by our partners at the OCSHCN. We then contact them by phone initially and go through the verbal consent over the phone. We do ask parents for additional contact methods, such as email or other contact, such a text messaging and make contact up to 5 times to participate if parent does not answer or requests return call initially. After one phone conversation, we may try to text the parent with general information to gauge further interest in participation. The text message would recall the research personnel he or she spoke to, a brief summary of the study and to contact research personnel if interested. The text would be sent only after initial contact to verify the parent phone number is correct. We will attach the contact form to initial OCSHCN referral form. We will not be going through any medical records at that OCSHCN clinic where there are going to be seen before, during, or after participation in the study. The participants provides any important medical information on the study questionnaire once informed consent is obtained. We do not have any physical contact with the proposed participants as they are likely many miles away and we do not have research personnel at the clinic. Doing the consent over the phone is the only practice way to enroll these subjects into the study in a timely manner. It is critical to do this asap because we have to involve them in the research activities within the first week or 2 after birth. If we do this by mail we will not be able to conduct this research. We will not be going through any medical records.

Aim 2 involves selected interview with certain parents or clinic staff, etc. These will be in person when possible and written informed consent is obtained for this Aim. Informed consent with parents, patient navigators and clinic administrators and personnel can include in-person or via phone/Zoom. If the parent, patient navigator or clinic administrator/personnel is unable to access REDCap, the consent will be emailed to the participant with allowance of time to review informed consent form, ask questions, and sign and date and return back to the study team with by a secure email or fax machine only accessible to research personnel. If the consenting process occurs by phone or Zoom, the parents, patient navigators or clinic administrators/personnel will be sent a link via REDCap to review & sign the consent while on the phone/Zoom with study personnel. A copy of the consent will either be emailed to them automatically via REDCap if consented electronically or the copy of the signed consent will be mailed or emailed to the participants.

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 is involving the recruitment of 1120 parent-infant dyads over the course of 4 years referred for hearing testing to Office for Children with Special Health Care Needs (OCSHCN) clinics all across the state of Kentucky. The research will occur within 10 OCSHCN clinic offices across the state. This is a expansion of research conducted within this location approved under IRB protocol. These patients are referred to those clinics from birthing hospitals at the time of birth because the child fails a newborn hearing test in the newborn nursery. This is one while the child is in the hospital but usually no more than 3-4 weeks after the child is born. Once the dyad is referred to that clinic, the clinic schedules them for their office visit in that OCSHCN clinic. The clinic staff (not any of our research personnel) ask the parent about being contacted by the research personnel and may insert a small flyer on the study that would accompany the appointment reminder if parent would like further information. If they agree to being contacted then the OCSHCN staff send the name and contact number of the dyad to our research staff to contact about participation in the study. We do not cold call anyone and we do not go through any records to identify subjects. The potential participants are given to us by our partners at the

OCSHCN. We then contact them by phone and go through the verbal consent over the phone. We do ask parents for additional contact methods, such as email or other contact, such as text messaging and make contact up to 5 times to participate if parent does not answer or requests return call initially. After one phone conversation, we may try to text the parent with general information to gauge further interest in participation. The text message would recall the research personnel he or she spoke to, a brief summary of the study and to contact research personnel if interested. The text would be sent only after initial contact to verify the parent phone number is correct. We will attach this form to initial OCSHCN referral form. We will not be going through any medical records at that OCSHCN clinic where there are going to be seen before, during, or after participation in the study. The participants provides any important medical information on the study questionnaire once informed consent is obtained. We do not have any physical contact with the proposed participants as they are likely many miles away and we do not have research personnel at the clinic. Doing the consent over the phone is the only practice way to enroll these subjects into the study in a timely manner. It is critical to do this asap because we have to involve them in the research activities within the first week or 2 after birth. If we do this by mail we will not be able to conduct this research. We will not be going through any medical records.

Aim 2 involves selected interview with certain parents or clinic staff, etc. These will be in person when possible and written informed consent is obtained for this Aim. Informed consent with parents, patient navigators and clinic administrators and personnel can include in-person or via phone/Zoom. If the parent, patient navigator or clinic administrator/personnel is unable to access REDCap, the consent will be emailed to the participant with allowance of time to review informed consent form, ask questions, and sign and date and return back to the study team with by a secure email or fax machine only accessible to research personnel. If the consenting process occurs by phone or Zoom, the parents, patient navigators or clinic administrators/personnel will be sent a link via REDCap to review & sign the consent while on the phone/Zoom with study personnel. A copy of the consent will either be emailed to them automatically via REDCap if consented electronically or the copy of the signed consent will be mailed or emailed to the participants.

When using the REDCap e-consent function, a member of the study team will connect with the potential participant either through phone or Zoom, depending on the participant's capabilities. This will allow for a member of the study team to go over the consent with the participant and answer any questions he or she may have during the consent process. While on the phone or via Zoom with the potential participant, the authorized study team member obtaining consent will go into the study's REDCap form designated for the participant arm and add a new record. Once the study team member has added a new record, he or she will complete the Recruiter data collection instrument. The study team member will put his or her first and last name in the designated boxes as well as put the potential study participant's email in the designated field as shown below. To automatically send the Consent link to the participant, the study team member will check Yes to the "Send consent email to participant" question. Once all of the four fields have been filled out, the study team member will mark the form as complete. Once this Recruiter from is marked as complete, the email containing the link to the e-consent in REDCap will automatically send to participants. The participant will then click on the link to complete the e-consent. Pages of the stamped version of the consent will display in chronological order. At the end, the participant will have to answer two questions. The first one being whether or not they consent to the study. The second question asks if the research team can contact them about future studies. Once the participant marks he or her answers, They have to use the signature function to sign their name. The participant will also have to select the date. Please note that the name of the authorized person obtaining consent is located before the Next Page button. This name is pulled using REDCap piping logic from the Recruiter form that is filled out initially by the study team member. Once the participant fills out all of the questions, he or she will then click Next Page. The next page is the e-consent certification page that is built into REDCap. This provides the participants a way to certify that the information they entered is correct and that by electronically signing this is equivalent to them signing a paper consent form. If everything looks correct, the participant will check the small box in the yellow box and click Submit. After they click Submit, a copy of the signed consent form is automatically sent to their email. Participants can click on the link to view & download the signed, certified consent form. Additionally, the PDF of the signed copy of the consent is also saved in REDCap under the File Repository function so that the study team can access them at any time. A study team member will review the signed consent to make sure everything looks correct. (Please see the REDCap e-consent instructions PDF located in the Additional Information/Materials section of the e-IRB application)
Flyer submitted for post-OCSHCN discussion with parent to give further printed information on the study before research personnel call for potential enrollment.

Attachments

Attach Type	File Name
Advertising	Bush_flyer_edited.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.

Specific Aim 1:

Clinics: All data collected on non-adherence to follow-up within 3 months after birth will be at the clinic level. The primary effectiveness outcome is the proportion of non-adherent referrals for diagnostic testing at each clinic during each month of the trial. The stepped-wedge design will allow us to monitor non-adherence trends throughout the control and intervention conditions for each clinic and the state as a whole over the entire course of the study. The effectiveness of PN to decrease non-adherence rates will be assessed via comparison of clinics' PN condition data to clinics' control (standard of care) condition data. The effectiveness data will be shared with the Community Advisory Board (CAB) as well as OCSHCN administration on a quarterly basis.

Parent-Infant Dyads: As part of the same phone call to obtain parental informed consent, a trained research assistant will administer baseline measures of knowledge of hearing loss, self-efficacy for obtaining follow-up testing, and perceived barriers to follow-up testing. Alternatively, the parent can choose to complete the baseline measures via REDCap links. Following completion of baseline measures, parents will be contacted by the PN to initiate intervention delivery. Post-test measures will be administered by phone by a research assistant or via REDCap 16 weeks after birth – one month after the 3-month target deadline for diagnostic testing has passed. The research assistant administering post-test measures will not have access to data regarding parents' follow-up with diagnostic testing. Parent participants will be compensated $20 for each set of completed measures (i.e., at baseline and at post-test assessment). These data will be shared with the CAB quarterly and recommendations on additional PN training or PN modifications will be observed. At no time during this study will prospective dyads be selected by examining medical records. Dyads will be referred by the various OCSHCN clinics, and not contacted by study personnel until that time. Additionally, no survey results, or interview information (if applicable), will be added to patient records and will only be held by research personnel for the time period required by the IRB before they are destroyed.

Parent-Infant Measures: Secondary effectiveness outcomes include parent participants' knowledge, self-efficacy, and barriers regarding obtaining follow-up diagnostic testing for their infant. We will also obtain EHDI data for all enrolled infants until their one-year birthday (or until data collection ends) to determine the time from birth to initial completed diagnostic assessment, number of no-show appointments, and number of rescheduled appointments. We will also collect data from EHDI to allow for control comparison of those infants who do not participate in the program to compare outcomes regarding follow-up diagnostic testing. From this control data, we will be conducting analyses looking at the impact of the COVID-19 pandemic on diagnostic testing and newborn hearing screening throughout the state of Kentucky. We will be comparing pre-COVID data with peri-COVID data. Additionally, we will look for racial & ethnic differences in the rates of follow up testing and screenings.

Specific Aim 2:

Patient Navigators: Baseline data collection from PNs will occur immediately following study enrollment and before PN training, administered by a trained interviewer. At the conclusion of PN training, PNs will take an examination to ensure comprehension of critical principles necessary for successful navigation. A score >80% will be required to pass the training. PNs with less than a passing score will be allowed to repeat relevant training elements and retake the examination one time; if the examination is not passed on the second round, the PN will no longer be employed in this study and a new PN will be identified. For those who pass the examination and proceed to intervention delivery, PNs will (1) audio-record 10% of PN sessions (with parent permission) to allow assessment of fidelity, (2) complete a PN fidelity checklist following each PN session, and (3) maintain process logs detailing time, travel, attendance, frequency and modes of contact with families, and other activities and expenses associated with PN delivery using provided checklists for every phone call interval, including initial call through termination. The checklists also provide opportunity for discussion of family adjustment, to establish rapport with the parent, hearing test expectations and clinic information, community resources and education on 1, 3, 6 and 12 month hearing health care. The checklists are a more comprehensive approach to the Patient Navigator Phone Call Guide and have only study numbers as identifiers on the forms. Approximately 6 months after completing PN training, PNs will complete post-test assessments and key informant interviews, administered via REDCap or by a trained interviewer. PNs will be compensated $25 at baseline and post-test for completing the battery of assessments. In each clinic, PN will continue after the 6-month assessment time point until the end of the 2nd quarter of Y5. These data will be shared with the CAB quarterly and recommendations on additional PN training or PN modifications will be observed.

Clinic Administrators, Staff, and Providers: Approximately 6 months after crossing to the PN condition, administrators, staff, and providers from each OCSHCN clinic will participate in key informant interviews conducted by a trained interviewer and complete quantitative measures either administered via REDCap links, over the phone, or by paper form in-person. These participants will be

compensated $25.

Parent Participants: At the Aim 1 post-test assessment (16 weeks post-birth), parents will complete a PN satisfaction measure. Selected parents (N~40) will also complete a 1-hour semi-structured key informant interview exploring parents' experiences with the PN intervention. Parents completing post-test measures will be compensated $20 under Aim 1, and parents completing interviews will be compensated an additional $25.

Measures: All instruments and interviews will be administered either via REDCap links, over the phone, or in person by trained interviewers/research personnel. Implementation outcomes of interest for this study include acceptability, adoption, appropriateness, feasibility, reach, and sustainability. Measures of each implementation outcome are summarized in Table 1 (p. 138 of attached grant proposal). CFIR implementation factors of interest are under four CFIR domains: PN characteristics, inner setting characteristics, and outer setting characteristics. Measures of each implementation factor are also summarized in Table 1. Qualitative key informant interviews will be used to complement newly developed quantitative measures, guided by the CFIR interview tool produced by the CFIR Research Team. Key informant interviews with parents, PNs, and clinic administrators/staff/providers will be audio-recorded with permission.

Specific Aim 3:

Costs: Both direct and indirect costs associated with PN will be included. Costs associated with the initial newborn hearing screen will be excluded from analyses since these costs are incurred for all infants regardless of outcomes. Direct costs include the cost of: PN establishment (PN recruitment and training costs), program implementation (office space, PN time, PN travel and tools, PN materials, PN supervision, staff turnover), parent time and travel (travel to seek diagnostic or PN services, time spent receiving diagnostic services), treatment costs (costs of a rescreen or diagnostic audiology appointment), nonmedical costs (potential cost savings due to earlier identification), and non-adherence costs for the clinics (no-show appointments). Research activity costs (e.g., data collection, human subject protection training of PNs) are not included. Indirect costs include opportunity costs of time (e.g. loss of productivity/wages) for the parent(s). Cost data will be collected and monitored annually throughout the study period, for both the intervention and standard of care conditions. Unit program costs will be documented as Aims 1 and 2 are implemented and sustained over the study period. Unit costs of PN and parent participant travel will be estimated using the distance between patient and clinic address/zip code multiplied by the standard GSA standard mileage rate and adding any lodging expenses (if applicable). Unit costs of PN time and PN supervision will be estimated using logs maintained by the PNs and supervisors, applying the hourly PN pay rate (or related rate for supervisor). Parent participant time will be estimated using the average wage rate for Kentucky (estimated using average wage data from the Bureau of Labor Statistics (BLS)). Unit treatment costs will be estimated using administrative charge data from the OCSHCN, aggregated at the clinic level. Unit cost savings associated with early identification will be estimated using data from the literature. Unit costs of non-adherence will be based on costs of PN time not used but spent (which may vary if services are centralized versus local) and staff costs associated with rescheduling as documented in staff logs. Loss of productivity will be estimated using an estimate of time away from work (calculated using driving distance) and lost wages for one parent, using BLS average wage statistics. Where cost related data are tied directly to PN reporting/logs, data will be reviewed and checked monthly to ensure consistency and check validity.

Effectiveness: The measured outcome of effectiveness to which costs will be compared is the proportion of individuals in each group who achieve diagnosis by 3 months of age. We will derive these outcome data using clinic-level non-adherence rates reported monthly by EHDI, collected in Aim 1.

Aim 1 is involving the recruitment of 1120 parent-infant dyads over the course of 4 years referred for hearing testing to Office for Children with Special Health Care Needs (OCSHCN) clinics all across the state of Kentucky. These patients are referred to those clinics from birthing hospitals at the time of birth because the child fails a newborn hearing test in the newborn nursery. This is one while the child is in the hospital but usually no more than 3-4 weeks after the child is born. Once the dyad is referred to that OCSHCN clinic, the clinic schedules them for their office visit in that clinic. The Commission staff (not any of our research personnel) ask the parent about being contacted by the research personnel and may insert a small flyer on the study that would accompany the appointment reminder if parent would like further information. If they agree to being contacted then the OCSHCN staff send the name and contact number of the dyad to our research staff to contact about participation in the study. We do not cold call anyone and we do not go through any records to identify subjects. The potential participants are given to us by our partners at the OCSHCN. We then contact them by phone and go through the verbal consent over the phone. We do ask parents for additional contact methods, such as email or other contact, such as text messaging and make contact up to 5 times to participate if parent does not answer or requests return call initially. After one phone conversation, we may try to text the parent with general information to gauge further interest in participation. The text message would recall the research personnel he or she spoke to, a brief summary of the study and to contact research personnel if interested. The text would be sent only after initial contact to verify the parent phone number is correct. We will not be going through any medical records at that OCSHCN clinic where there are going to be seen before, during, or after participation in the study. The participants provides any important medical information on the study questionnaire once informed consent is obtained. We do not have any physical contact with the proposed participants as they are likely many miles away and we do not have research personnel at the clinic. Doing the consent over the phone is the only practice way to enroll these subjects into the study in a timely manner. It is critical to do this asap because we have to involve them in the research activities within the first week or 2 after birth. If we do this by mail we will not be able to conduct this research. We will not be going through any medical records.

Aim 2 involves selected interview with certain parents or clinic staff, etc. These will be in person when possible and written informed consent is obtained for this Aim. Informed consent with parents, patient navigators and clinic administrators and personnel can include in-person or via phone/Zoom. If the parent, patient navigator or clinic administrator/personnel is unable to access REDCap, the consent will be emailed to the participant with allowance of time to review informed consent form, ask questions, and sign and date and return back to the study team with by a secure email or fax machine only accessible to research personnel. If the consenting process occurs by phone or Zoom, the parents, patient navigators or clinic administrators/personnel will be sent a link via REDCap to review &

sign the consent while on the phone/Zoom with study personnel. A copy of the consent will either be emailed to them automatically via REDCap if consented electronically or the copy of the signed consent will be mailed or emailed to the participants.

When using the REDCap e-consent function, a member of the study team will connect with the potential participant either through phone or Zoom, depending on the participant's capabilities. This will allow for a member of the study team to go over the consent with the participant and answer any questions he or she may have during the consent process. While on the phone or via Zoom with the potential participant, the authorized study team member obtaining consent will go into the study's REDCap form designated for the participant arm and add a new record. Once the study team member has added a new record, he or she will complete the Recruiter data collection instrument. The study team member will put his or her first and last name in the designated boxes as well as put the potential study participant's email in the designated field as shown below. To automatically send the Consent link to the participant, the study team member will check Yes to the "Send consent email to participant" question. Once all of the four fields have been filled out, the study team member will mark the form as complete. Once this Recruiter from is marked as complete, the email containing the link to the e-consent in REDCap will automatically send to participants. The participant will then click on the link to complete the e-consent. Pages of the stamped version of the consent will display in chronological order. At the end, the participant will have to answer two questions. The first one being whether or not they consent to the study. The second question asks if the research team can contact them about future studies. Once the participant marks he or her answers, They have to use the signature function to sign their name. The participant will also have to select the date. Please note that the name of the authorized person obtaining consent is located before the Next Page button. This name is pulled using REDCap piping logic from the Recruiter form that is filled out initially by the study team member. Once the participant fills out all of the questions, he or she will then click Next Page. The next page is the e-consent certification page that is built into REDCap. This provides the participants a way to certify that the information they entered is correct and that by electronically signing this is equivalent to them signing a paper consent form. If everything looks correct, the participant will check the small box in the yellow box and click Submit. After they click Submit, a copy of the signed consent form is automatically sent to their email. Participants can click on the link to view & download the signed, certified consent form. Additionally, the PDF of the signed copy of the consent is also saved in REDCap under the File Repository function so that the study team can access them at any time. A study team member will review the signed consent to make sure everything looks correct. (Please see the REDCap e-consent instructions PDF located in the Additional Information/Materials section of the e-IRB application)

The research will occur within 10 OCSHCN clinic offices across the state. This is a expansion of research conducted within this location approved under IRB protocol.

Attachments

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 Attachments

Attachments

Attach Type	File Name
DataCollection	Self-efficacy measure The Patient Navigator Performance Checklist revised.pdf
DataCollection	Aim 1 phone script.pdf
DataCollection	Parent Phone Contact Documentation.pdf
DataCollection	Weiner Questionnaire (revised for PN).pdf
DataCollection	ORCA_PN_highlighted.pdf
DataCollection	ORCA_PN_clean.pdf
DataCollection	PCIS for Navigators.pdf
DataCollection	Navigator_Satisfaction_Survey_FINAL.pdf
DataCollection	Aim 1 Entrance_FINAL.pdf
DataCollection	Aim 1 Exit_FINAL.pdf
DataCollection	CASES FINAL - pre and post training and post intervention CHWs.pdf
DataCollection	EBPAS-50_FINAL - pre training and post intervention.pdf
DataCollection	PSAT.pdf
DataCollection	Fidelity Checklist.pdf
DataCollection	Patient Navigator Phone Call Guide.pdf

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.

Remote clinics will only be performing standard care and will not be altering any process for this study EXCEPT to notify the study personnel of a failed or irregular newborn hearing screen so that a navigator may be assigned.

The study does not require any special space. A patient navigator is not expected to be a care provider in this study, but rather an advocate for patients to identify concerns or questions, and to help patients navigate through the healthcare system. A phone in a private area of the Audiology clinic will be utilized with an encrypted, password protected computer for data collection and entry. The patient navigator has specialized skill to work with families who have a child with hearing loss and follows Good Clinical Practice when speaking with families. Research staff have experience and training in clinical research and utilize the principles of Good Clinical Practice when screening and enrolling. All have completed appropriate and documented Human Subjects Protection training.

Cyracom is an American Translators Association language interpretation and translation telephone service widely used in medical practice to assist in reaching people who do not speak English. University of Kentucky Healthcare system utilizes this phone approach for medical interpretation and translation and can be used for any language either over the phone or in direct contact. Cyracom also provides translated documentation that is certified and provide attestation to the accuracy of services.

We will also be using REDCap to collect and store data for this study. REDCap is a secure web platform for building and managing online databases and surveys. Only members of the study team will be granted access to the REDCap database.

Liza Creel, PhD, is being added from the University of Louisville as a co-investigator and will be relied upon for her expertise and advice.

Ryleigh Board is a college student from Campbellsville University who will be helping with the study in data collection, recruitment, and other study processes for the summer of 2021. A reliance agreement was executed & signed.

The research will occur within 10 OCSHCN clinic offices across the state. This is a expansion of research conducted within this location approved under IRB protocol.

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.

Although all research involving human subjects contains some risk, there are no known serious risks anticipated from participating in this study. One risk presented by this study is a potential breach of confidentiality, including the risk of Protected Health Information (PHI) being seen by someone unauthorized to do so. PHI is individually identifiable health information transmitted or maintained in any form (electronic means, on paper or through oral communication) that relates to the past, present, or future physical or mental health conditions of an individual that may be used or disclosed. The PHI collected throughout the course of this project includes: names, addresses, birthdates, appointment dates, and telephone numbers. As described throughout this document, many precautions are planned to guard against violations of participant confidentiality. All research personnel will be trained in human subjects protection and HIPAA compliance.

The PNs are community-based research personnel who will be carefully trained to help patients by answering questions and guiding them through the diagnostic and therapeutic process of receiving hearing healthcare. In order to prevent miscommunication, they will not be allowed to provide medical advice but instead will facilitate contact with healthcare providers. Implementation measures (e.g., EBPAS-50, CASES) collected from PNs at baseline and post-test will be considered research measures and will not affect their employment in the study. However, a score >80% on the post-training PN knowledge assessment will be required to pass the training. PNs with less than a passing score will be allowed to repeat relevant training elements and retake the examination one time; if the examination is not passed on the second round, the PN will no longer be employed in this study and a new PN will be identified. It is

possible that a breach of confidentiality revealing a PN's participation could cause the participant to experience discomfort regarding violated privacy, or social consequences such as perceived stigma or judgment by others.

For clinic administrators, staff members, or hearing healthcare providers who participate in Aim 2, the risks associated with breaches of confidentiality primarily involve risks to employment and/or professional relationships. If they share negative information about their perceptions of their agencies, colleagues, or organizational leadership, 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.
Participation in the study involves minimal risk for participants in comparison to the potential benefits. Potential benefits include: improvement in early detection and intervention of hearing loss in children, improvement in the awareness of hearing loss in children, and reduction of community and cultural barriers between patients and the healthcare system.

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).

Patients that choose not to participate in this research will be referred according to the standard of care to the regional hearing screening location according to state policies.

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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

Paper copies of the data, consents, and questionnaires will be kept in the locked offices of the research team (Kentucky Clinic Building, 3rd Floor, Suites B345, B347, B348, B361, or B365). All electronic forms of the data will be saved in password-protected servers and databases. These materials will be retained during the study and 6 years after the conclusion of the study. Consents that are returned electronically are sent through an encrypted email or a fax machine in a locked office that are only accessible through research personnel.
Paper copies of the data, consents, and questionnaires will be kept in the locked offices of the research team (Kentucky Clinic Building, 3rd Floor, Suites B345, B347, B348, B361, or B365). All electronic forms of the data will be saved in password-protected servers and databases. These materials will be retained during the study and 6 years after the conclusion of the study. Consents that are returned electronically are sent through an encrypted email or a fax machine in a locked office that are only accessible through research personnel. The documents will be disposed of in a HIPAA-approved receptacle that is used to dispose of confidential patient documents in our ENT clinic at UK.
(See pp. 154 -156 of attached grant submission)

As described above, staff at the OCSHCN will identify all infant referrals to a clinic in the intervention period and provide parent contact information to the UK research team. A CITI-trained interviewer with experience in recruiting and enrolling participants in human subjects research will describe the study, screen the parent-child dyad for eligibility, and invite eligible dyads to enroll in the study. Verbal informed consent for study participation will be obtained at that time from the parent of the eligible child on behalf of the parent and of the child. The infant will not be able to provide assent. This study will require a waiver of documentation of informed consent, as it is not feasible to obtain the written consent of all participants due to the large number and distance between OCSHCN clinics and the University of Kentucky. Appropriate measures and care will be taken in the recruitment of research participants from vulnerable populations. Regarding the recruitment of parent participants under 18 years of age and their infant children, the participant may give consent for services for her/his child and herself/himself without the consent of the participant's parent or legal representative

(according to KRS 214.145). We will also recruit infants who are wards of the state by contacting the local Department for Community Based Services (DCBS) Social Services Worker (SSW) or supervisor. The SSW or supervisor will determine the type of custody designation the child has been assigned and identify an advocate for the infant in addition to any other individual acting on behalf of the child as guardian or in loco parentis. Informed consent will be obtained from the advocate and the guardian of the infant, as mandated by the DCBS.

All participants will be individually informed about the study aims and procedures. The following areas will be explained in detail: why they are being invited to participate, who is conducting the research, the purpose of the study, inclusion and exclusion criteria, study location, time commitment, what they will be asked to do, permission to access the infant's hearing data from the Early Hearing Detection and Intervention database, risks and benefits in participating, the voluntary nature of the study, costs participation may incur, confidentiality, their right to end participation early, payment for participation, and contact information of the PI and Office of Research Integrity for any questions, suggestions, concerns, or complaints. The research staff conducting the consent interview will record that they have obtained verbal consent from the participant and the date on which it occurred. A separate consent process will occur for parents who agree to participate in qualitative interviews, covering the same areas of detail. Written consent will be obtained in this case immediately preceding the interview.

Written informed consent will be required for parents participating in qualitative interviews, for PNs (for their participation in baseline and post-test research measures), and for clinic administrators, staff, and providers. A CITI-trained interviewer will provide a written copy of a consent document written in a basic language and will also verbally review the following: why they are being invited to participate, who is conducting the research, the purpose of the study, inclusion and exclusion criteria, study location, time commitment, what they will be asked to do, risks and benefits in participating, the voluntary nature of the study, costs participation may incur, confidentiality, their right to end participation early, payment for participation, and contact information of the PI and Office of Research Integrity for any questions, suggestions, concerns, or complaints. A copy of the signed informed consent document will be provided to the participant.

Every effort will be made throughout the duration of the research project to protect against potential risks. Prior to study participation, we will make sure the participant is comfortable with the explanations of the purpose, duration, benefits, and risks presented to them. A phone script, written in basic language, will be used for recruitment to ensure all participants are able to adequately understand all aspects of the study. All participants will be reminded that all parts of the study are voluntary and that they do not have to answer anything they do not want to and can stop participating at any time. Although it is very unlikely, all participants will be given a contact name and number to call for additional information in case they are injured or become ill as a result of study participation. They will also be given a contact number for additional information about the rights of a participant in this study.
All physical copies of data collected from study participants will be kept in passcode-protected databased and lock-boxes or in the locked office of the PI. This data will be kept separate from any identifiers and will use the assigned identification number of each corresponding participant. All electronic forms of data collected will be kept on password-protected computers and in the password-protected REDCap application. Only research staff will be able to access the data, all of whom will have human subject protection training. The link file (containing both ID numbers and identifiers) for study participants will be kept on REDCap and access will only be granted to key study personnel. All subject PHI is confidential and will be protected according to the guidelines of the Health Information Portability and Accountability Act (HIPAA).

The PNs will be considered research participants (i.e., they will complete baseline and post-test quantitative research measures) in addition to being considered UK hourly employees for their time spent in training and in delivery of navigation service to parents. Prior to study participation, we will make sure all PNs understand that their responses to research measures will not affect their employment on the study, with the exception of their post-training examination score.

Because PNs will directly engage with parent research participants and will be implementing aspects of the research protocol, PNs will be trained using the CIRTification human subject protection training program designed and made available by the University of Illinois at Chicago from their Center for Clinical and Translational Science (http://www.ccts.uic.edu/content/cirtification). This training is designed specifically for community partners from non-academic settings and includes an in-person training curriculum focused on the history of human subject protections, privacy and confidentiality, justice and beneficence, and other research issues. The CIRTification training will be incorporated into the PNs initial training. This research team has successfully used the CIRTification training with community-based research partners and interventionists in prior studies. Additionally, in order to address the potential risk of miscommunication between a PN and study participant in regards to giving medical advice, PNs will be given contact information of various healthcare professionals trained to adequately answer and guide patients with specific medical concerns.

UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Do you confirm that you will retain all IRB-related records for a minimum of 6 years after study closure?

◉ Yes ○ No

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.

Aim 1: Parent participants will be compensated $20 for each set of completed measures (i.e., at baseline and at post-test assessment). These data will be shared with the CAB quarterly and recommendations on additional PN training or PN modifications will be observed.

Aim 2: PNs will be compensated $25 at baseline and post-test for completing the battery of assessments. In each clinic, PN will continue after the 6-month assessment time point until the end of the 2nd quarter of Y5. These data will be shared with the CAB quarterly and recommendations on additional PN training or PN modifications will be observed.

Aim 2 Clinic Administrators, Staff, and Providers: Approximately 6 months after crossing to the PN condition, administrators, staff, and providers from each clinic will participate in key informant interviews and complete quantitative measures administered by a trained interviewer. These participants will be compensated $25.

Aim 2 Parent Participants: At the Aim 1 post-test assessment (16 weeks post-birth), parents will complete a PN satisfaction measure. Selected parents (N~40) will also complete a 1-hour semi-structured key informant interview exploring parents' experiences with the PN intervention. Parents completing post-test measures will be compensated $20 under Aim 1, and parents completing interviews will be compensated an additional $25.

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 is no cost to patients for involvement in this research.

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.

(See pages 157 - 159 of the attached grant submission form)

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 obtain self-reported data via phone interviews and quantitative paper-based questionnaires, and we will conduct key informant interviews. Patient navigation will involve phone contact between a parent and a navigator to assist in facilitating timely diagnostic care. All study personnel (i.e., investigators, collaborators, and navigators) 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 adverse events (AE) include:
• Distress from answering questions about child hearing problems
• Required breach of confidentiality due to domestic violence and/or child abuse reporting laws

Any AE will be immediately reported to the PI, the IRB, and NIH. Referrals for professional services (e.g., counseling) will be provided to any impacted participants. Local referral lists for counseling services will be developed for each community, and Co-Investigator Dr. Tina Studts, who worked for nearly a decade as a licensed clinical social worker (LCSW) will facilitate these referrals.

Description of safety monitoring:

The study will involve 1120 parent-infant dyads, 30 patient navigators, and 30 clinic administrators, staff members, or hearing healthcare providers. We will conduct no medically intrusive screenings or interventions.

Appropriate measures and care will be taken in the recruitment of research participants from vulnerable populations. According to Kentucky state law, in the recruitment of parent participants under 18 years of age and their infant children, the participant may give consent for services for her/his child and herself/himself without the consent of the participant's parent or legal representative. This applies to research of minimal risk. We will also recruit infants who are wards of the state with the following special precautions. According to Kentucky state law, wards of the state will be recruited by identifying an advocate for the infant in addition to any other individual acting on behalf of the child as guardian or in loco parentis. This advocate will be an individual who has a background and

experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way with the research, the investigator(s), or the guardian organization.

Dr. Bush (PI), Dr. Shinn (Co-I), and Ms. Lester (Co-I) have extensive experience working with infants with hearing loss and in working with their parents. Dr. Studts (Co-I) has extensive experience working in communities and administering community-based interventions, and all have had no safety concerns in the past. It is possible that some psychological distress will result from enrollment in the study. While this is extremely rare, with input from each OCSHCN clinic, we will develop a referral list of local counseling services for each community that is serviced by a OCSHCN clinic. If a participant is in need of counseling, all she/he need do is to inform Dr. Bush (PI), who will arrange a counseling session. If the participant experiences psychological discomfort with the interview, he or she will be reminded that she need not complete the protocol and has the right to withdraw from the study at any time.

The other 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, 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 PI, Dr. Bush, who will be responsible for (1) reporting AE to the IRB and NIH, (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 navigators, research assistants, investigators, and collaborators will be trained to recognize an AE and to undertake the proper reporting protocols in the event of an AE. Additionally, Dr. Studts 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 a 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 re-consent 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:

Any adverse event (AE) will be classified by the PI as serious or non-serious, and appropriate reporting procedures followed. Dr. Bush will report any AE to the appropriate program officer at the NIH and to the UK Human Subjects Office in writing within five working days. Dr. Bush will also prepare the summary of all Adverse Events for the project's duration. The written AE report will also be sent to the University Of Kentucky Office Of Research Integrity Interim Director, Ms. Helene Lake-Bullock, Phone: 859-257-9428 Email: hlbullo@uky.edu. Any serious adverse event will be reported immediately.

Reporting of other study-safety events:

As the study is being conducted, the PI will also inform the NIH 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 NIH program officer 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 subject 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 five-digit identifying number (clinic randomization number: example 01 and subject study number: example 001.
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. Personnel must successfully complete the CITI or Protecting Volunteers in Research Training.

The Principal Investigator, Matthew L. Bush, M.D. will be responsible for monitoring the safety of the subjects involved. Dr. Bush will work with Dr. Judy Theriot (medical director of the OCSHCN - see letter of support) to ensure safety of the participants. The PI will provide a summary of the DSM report to NIH on an annual basis as part of the progress report. The DSM report will include the subjects' sociodemographic characteristics, expected versus actual recruitment rates, retention rates, any quality assurance or regulatory issues that occurred during the past year, summary of adverse events (AEs) and serious adverse events (SAEs) and any actions or changes with respect to the protocol. We will make every effort to keep private all research records. The questionnaires, informed consents, and any other study documents will be kept in the locked office of the PI at the University of Kentucky. The same office will contain a password-protected computer that will house electronic data of the subjects. Subject that experience an adverse event or emotional distress will be instructed to call Matthew L. Bush, M.D. at 859-257-5097 immediately. Further questions, suggestions, concerns, or complaints about the study, can be addressed by the staff in the Office of Research Integrity at the University of Kentucky at 859- 257-9428 or toll free at 1-866-400-9428.

Data and Safety Monitoring Board (DSMB).

NIH requires the establishment of Data and Safety Monitoring Boards (DSMBs) for 1) multi-site clinical trials involving interventions that entail potential risk to the participants, and 2) for most Phase III clinical trials. This project meets neither of these definitions and, therefore, it is likely that a DSMB may not be required. This project only involves minimal level of risk of the proposed project. A board (DSMB) will be established to review this study and follow the SOP designated by the UK Office of Research Integrity and the IRB. The CCTS has an established DSMB who will serve the role of an impartial board who have expertise with these studies but who can oversee safety without bias. The DSMB will meet semiannually or as needed. The DSMB will review subject recruitment, AE's, side effects, laboratory results, dropouts, protocol violations, and inclusion/exclusion criteria. More frequent meetings will take place if side effects or other problems are prevalent.

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

No data from the study will be used in future studies.

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

We will be utilizing Cyracom to translate the Informed Consent Form and research procedures, including navigator phone follow up and Aim 2 consent and phone questionnaire. Sarah Hesler, University of Kentucky Medical Center Interpreting Services manager, has recommended Cyracom to utilize for language interpreting, as they are ATA (American Translators Association) certified. Cyracom is a telephone interpreting service for any non-English language speaking individuals that allows the caller (Commission, research personnel or navigators) to speak directly to a parent utilizing a 3-way conference calling system. Cyracom is widely used in the medical setting to interpret medical information. Research can reach many different non-English speaking potential subjects and allow them to participate if desired using Cyracom in this study. Parents who desire to participate in Aim 2 portion of the study will be given the consent form in their preferred language as a short form translation that has attestation and is certified by Cyracom.

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-Sponsored 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 all 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.)

If yes, check below all that apply and attach the applicable document(s):

- ☐ HIPAA De-identification Certification Form
- ☐ HIPAA Waiver of Authorization

Attachments

STUDY DRUG INFORMATION

0 unresolved comment(s)

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).

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)

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 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.
- 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:

The research will occur within the Kentucky Office for Children with Special Health Care Needs (OCSHCN), formerly, the Commission for Children with Special Health Care Needs. The research will occur within 10 OCSHCN clinic offices across the state. This is a expansion of research conducted within this location approved under IRB protocol. A fully executed contracted has been completed. The medical director has approved the research to be conducted on site (attached letter) and the executed contract with the OCSHCN has been completed (attached). The University of Louisville will participate in the cost-effective aim of this research study. A fully executed contracted has been completed and uploaded into the Additional Information section.

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

Attachments

Attach Type	File Name
-IRB Authorization Agreement	E-IRB 47997 Bush Signed IAA with KCHFSpdf.pdf
-Letter of Support & Local Context	Fully Executed Agreement M337.pdf
-Letter of Support & Local Context	Theriot LOS scan.pdf

B) Is this a multi-site study for which **you are the lead investigator or UK is the lead site**? ○ Yes ◉ No

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

C) 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)

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

	For additional requirements and information:
☐ Academic Degree/Required Research	• Cancer Research (MCC PRMC) • Certificate of Confidentiality (look up "Confidentiality/Privacy...") • CCTS (Center for Clinical and Translational Science)
☐ Alcohol/Drug/Substance Abuse Research	• Clinical Research (look up "What is the definition of....)
☐ Biological Specimen Bank Creation (for sharing)	• Clinical Trial
☐ Cancer Research	• Collection of Biological Specimens for Banking (look up "Specimen/Tissue Collection...")
☐ CCTS-Center for Clinical & Translational Science	• Collection of Biological Specimens (look up "Specimen/Tissue Collection...")
☐ Certificate of Confidentiality	• Community-Based Participatory Research (look up "Community-Engaged...")
☑ Clinical Research	• Data & Safety Monitoring Board (DSMB) *For Medical IRB: Service Request Form for CCTS DSMB
☐ Clinical Trial - Phase 1	• Data & Safety Monitoring Plan
☑ Clinical Trial	• Deception* *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"
☐ Collection of Biological Specimens for internal banking and use (not sharing)	• Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
☑ Community-Based Participatory Research	• Genetic Research (look up "Specimen/Tissue Collection...")
☐ Deception	• Gene Transfer
☐ Educational/Student Records (e.g., GPA, test scores)	• HIV/AIDS Research (look up "Reportable Diseases/Conditions")
☐ Emergency Use (Single Patient)	• Screening for Reportable Diseases [E2.0000] (PDF)
☐ Gene Transfer	• International Research (look up "International & Non-English Speaking")
☐ Genetic Research	• NIH Genomic Data Sharing (GDS) Policy (PDF)
☐ GWAS (Genome-Wide Association Study) or NIH Genomic Data Sharing (GDS)	• Planned Emergency Research Involving Waiver of 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"
☐ Human Cells, Tissues, and Cellular and Tissue Based Products	• Use, storage and disposal of radioactive material and radiation producing devices
☐ 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	

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]
- 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.):

NIDCD

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	Full app_printed from ERA commons 6.5.18.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 and attach form
- 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.**

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	E-IRB 47997 CR 2024 Bush Signed 310 Form.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:

First Name	Last Name	Role	Department	Date Signed	
Raleigh	Jones	Department Authorization	Otolaryngology	11/14/2018 08:24 AM	View/Sign
Matthew	Bush	Principal Investigator	Otolaryngology	11/21/2018 11:09 AM	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). Please notify the personnel required for signing your IRB application after sending for signatures. Once all signatures have been recorded, you will need to 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		0.081	klars2	9/4/2024 10:12:51 AM
	AddInfoProduct	E-IRB 47997 CR 2024 Bush Signed 310 Form.pdf	Newest signed 310 Form CR 2024	0.286	klars2	3/14/2024 9:57:50 AM
	AdditionInfoConsiderations	E-IRB 47997 New Signed 310 Form CR 2022.pdf	Newest signed 310 Form	0.261	klars2	6/22/2022 3:15:43 PM
	AdditionInfoConsiderations	E-IRB 47997 PI Bush New Signed 310 Form CR 2021.pdf	Signed 310 Form	0.308	klars2	9/1/2021 1:50:23 PM
	AdditionInfoConsiderations	2019-011 Bush-Creel IAA - fully executed.pdf	Fully Executed IAA UofL Bush-Creel	0.063	mrsc243	6/30/2021 9:23:56 AM
	AdditionInfoConsiderations	Individual Investigator Agreement_Ryleigh Board_47997.pdf	IRBReliance Agreement for Ryleigh Board	0.322	mrsc243	6/29/2021 10:20:39 AM
	AdditionInfoConsiderations	REDCap e-consent instructions v2.pdf	REDCap e-consent instructions	0.742	mrsc243	1/27/2021 11:46:46 AM
	DataCollection	Self-efficacy measure The Patient Navigator Performance Checklist revised.pdf	Self Efficacy measure	0.141	mrsc243	1/12/2021 12:00:31 PM
	DataCollection	Aim 1 phone script.pdf	Aim 1 Parent Phone Script	0.209	mlhatf0	12/14/2020 10:37:17 AM
	Advertising	Bush_flyer_edited.pdf	Bush_Flyer_Edited_phone number change	0.258	mlhatf0	12/14/2020 10:35:57 AM
	AdditionInfoConsiderations	E-IRB 47997 CR 2020 Bush Signed HHS 310 Form.pdf	Signed 310 Form	0.129	klars2	11/4/2020 7:40:31 AM
	AdditionInfoConsiderations	Letter insert for OCSHCN (CHHIRP).docx	Flyer for letter insert	0.057	mlhatf0	10/23/2020 11:38:20 AM
	AdditionInfoConsiderations	Memo to accompany CR 2020.pdf	Memo for Continuation Review 10-20-20	0.076	mlhatf0	10/20/2020 2:39:50 PM
	AdditionInfoConsiderations	Self-efficacy measure The Patient Navigator Performance Checklist-TS Edits.pdf	PN Self-Efficacy Measure (TS)	0.138	mlhatf0	10/20/2020 1:18:41 PM
	AdditionInfoConsiderations	Fidelity measure The Patient Navigator Performance Checklist-TS Edits.pdf	PN Fidelity Checklist (TS)	0.156	mlhatf0	10/20/2020 1:18:02 PM
	AdditionInfoConsiderations	CHHIRP_Text_Script.docx	Text_Message_Script	0.016	mlhatf0	4/9/2020 10:45:33 AM
	DataCollection	Parent Phone Contact Documentation.pdf	Parent_Phone_Contact_Documentation	0.018	mlhatf0	3/18/2020 2:21:59 PM
	AdditionInfoConsiderations	CHHIRP - UK Communication Plan Form for Bush (Studts reliance).pdf	CHHIRP_UK_Communication_Plan_Bush	0.306	mlhatf0	3/12/2020 11:53:32 AM
	AdditionInfoConsiderations	CHHIRP - UK Relying Site Form when UK Reviews (Studts reliance).pdf	CHHIRP_Studts_Reliance_Agreement_Site_Form_UK	0.233	mlhatf0	3/12/2020 11:51:45 AM
	AdditionInfoConsiderations	CHHIRP - Studts Reliance Agreement.pdf	CHHIRP_Studts_Reliance_Agreement	0.040	mlhatf0	3/12/2020 11:50:10 AM
	DataCollection	PCIS for Navigators.pdf	PCIS_Navigators	0.144	mlhatf0	3/6/2020 2:51:50 PM
	DataCollection	ORCA_PN_clean.pdf	ORCA_PN	0.237	mlhatf0	3/6/2020 2:46:11 PM
	DataCollection	ORCA_PN_highlighted.pdf	ORCA_PN_highlighted	0.242	mlhatf0	3/6/2020 2:44:22 PM
	DataCollection	Weiner Questionnaire (revised for PN).pdf	Weiner_Questionnaire_Revised	0.131	mlhatf0	2/28/2020 2:55:20 PM
	AdditionInfoConsiderations	PN Call 6 Termination Checklist_v2.pdf	Navigator_Call_Guide_6_v2	0.193	mlhatf0	2/28/2020 2:49:55 PM
	AdditionInfoConsiderations	PN Call 5 Checklist_v2.pdf	Navigator_Call_Guide_5_v2	0.196	mlhatf0	2/28/2020 2:48:02 PM
	AdditionInfoConsiderations	PN Call 4 Checklist_v2.pdf	Navigator_Call_Guide_4_v2	0.196	mlhatf0	2/28/2020 2:46:23 PM
	AdditionInfoConsiderations	PN Call 3 Checklist_v2.pdf	Navigator_Call_Guide_3_v2	0.191	mlhatf0	2/28/2020 2:43:25 PM
	AdditionInfoConsiderations	PN Call 2 Checklist_v2.pdf	Navigator_Call_Guide_2_v2	0.248	mlhatf0	2/28/2020 2:40:42 PM
	DataCollection	Aim 1 Exit_FINAL.pdf	Aim_1_Exit_Survey_Parents	0.088	mlhatf0	2/13/2020 2:06:46 PM
	DataCollection	Aim 1 Entrance_FINAL.pdf	Aim_1_Entrance_Survey_Parents	0.083	mlhatf0	2/13/2020 2:06:02 PM

DataCollection	Navigator_Satisfaction_Survey_FINAL.pdf	Navigator_Satisfaction_Survey_Parents	0.123	mlhatf0	2/12/2020 4:48:23 PM
AdditionInfoConsiderations	PN Initial Call 1 Checklist.pdf	Navigator_Call_Guide_1	0.056	mlhatf0	2/6/2020 11:19:13 AM
AdditionInfoConsiderations	EBPAS-50 (clean) 12-16-19.pdf	EBPAS-50 (clean) revisions	0.047	mlhatf0	12/16/2019 12:26:48 PM
AdditionInfoConsiderations	EBPAS-50 (highlighted)12-16-19.pdf	EBPAS-50 (highlighted) revisions	0.051	mlhatf0	12/16/2019 12:25:17 PM
AdditionInfoConsiderations	EBPAS-50_FINAL - pre training and post intervention.pdf	EPBAS-50	0.194	mlhatf0	12/16/2019 12:24:12 PM
AdditionInfoConsiderations	E-IRB 47997 Signed HHS 310 Form.pdf	Signed 310 Form	0.521	klars2	12/9/2019 2:02:31 PM
AdditionInfoConsiderations	Lori_Travis_NIHtraining_Human_Protection.pdf	Lori Travis Human Protection Certificate	0.043	kpdyer2	7/24/2019 10:35:44 AM
AdditionInfoConsiderations	Creel_citiCompletionReport3519386_expires05-10-2023.pdf	Liza Creel CITI Training	0.404	kpdyer2	6/27/2019 2:16:35 PM
AdditionInfoConsiderations	IRB-IEC_6-17-2019_2019-011 Bush-Creel IAA - fully executed.pdf	Latest Revision IRB/IEC Authorization Agreement	0.063	kpdyer2	6/27/2019 2:16:16 PM
AdditionInfoConsiderations	IRB Authorizaation Agreement (IAA) - Matthew Bush M.D. (UK) (002).pdf	IRB/IEC Authorization Agreement	0.063	kpdyer2	5/30/2019 2:03:21 PM
AdditionInfoConsiderations	E-IRB 47997 Bush 310 Form.pdf	Signed 310 Form	0.517	klars2	2/12/2019 1:56:02 PM
-IRB Authorization Agreement	E-IRB 47997 Bush Signed IAA with KCHFSpdf.pdf	IAA	0.067	klars2	12/4/2018 1:28:30 PM
DataCollection	Patient Navigator Phone Call Guide.pdf	Navigator Phone Call Guide	0.084	kpdyer2	11/20/2018 4:01:46 PM
DataCollection	Fidelity Checklist.pdf	Fidelity of Patient Navigator Checklist	0.137	kpdyer2	11/20/2018 4:00:59 PM
DataCollection	PSAT.pdf	Program_Sustainability_Assessment_Tool_PSAT	0.243	kpdyer2	11/15/2018 1:16:17 PM
DataCollection	EBPAS-50_FINAL - pre training and post intervention.pdf	Evidence Based Practice Attitude Scale	0.194	kpdyer2	11/15/2018 1:09:04 PM
DataCollection	CASES FINAL - pre and post training and post intervention CHWs.pdf	Case Management Skills Assessment	0.205	kpdyer2	11/15/2018 1:08:12 PM
GrantContract	Full app_printed from ERA commons 6.5.18.pdf	NIH full grant application	5.736	mlbush2	11/13/2018 4:07:06 PM
-Letter of Support & Local Context	Theriot LOS scan.pdf	Commission Medical Director LOS	0.046	mlbush2	11/13/2018 3:37:10 PM
-Letter of Support & Local Context	Fully Executed Agreement M337.pdf	Commission Research Subaward Contract	0.133	mlbush2	11/13/2018 3:36:15 PM

Protocol Changes

Protocol Number: 47997

No Changes
There are no recorded changes tracked for this protocol.

Study Personnel Changes:

Status	PPIdentity	ProtocolID	PersonID	RoleInProtocol	IsContact	LastName	FirstName	Email	DeptCode	RoomBuilding	SpeedSort	PhoneNum	DeptDesc	AuthorizedConsent	ResponsibilityInProject	Degree	Rank	StatusFlag	IsRemoved	ModBy	ModDate	SFI	IsPIRN	MiddleName
Inserted	919778	99142	12199096	DP	N	Reedy-Johnson	Melissa	Melissa.Reedy-Johnson1@uky.edu						Y	Project Assistance/Support			P	N	lpbe223	9/4/2024 9:34:23 AM	N		

No comments