

PROTOCOL AND STATISTICAL ANALYSIS PLAN

Study Title: Promoting Early Diagnosis of Congenital Hearing Loss with Patient Navigators

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Sample Size Calculation and Recruitment: In order to expand the generalizability of this research, we have elected to investigate the efficacy of patient navigation in both Appalachian and non-Appalachian subjects. Non-adherence is a significant problem throughout Kentucky, but more problematic in Appalachia, so we propose to assess the efficacy of a patient navigator in two strata of the same clinical trial (Appalachian and non-Appalachian populations). We have found non-adherence to obtain diagnostic testing after failed infant hearing screen in 27% and 15% of Appalachian and non-Appalachian children, respectively.² We propose that the navigator program will be equally effective on the odds of non-adherence in each of the two strata. Specifically, assuming a common odds ratio of 0.36, we expect the navigator program to decrease nonadherence to 12% and 6% in the Appalachian and non-Appalachian populations, respectively. In order to have 80% power when carrying out a one-tailed Cochran-Mantel Haenszel (CMH) test at the 0.05 significance level, we need 226 subjects, 90 (40%) of whom are from the Appalachian population. We expect that participants may leave the study if they chose to obtain their child's diagnostic testing at another facility outside UK; therefore, we have allowed for a 20% dropout rate. The goal total sample size is 284 participants (114 from the Appalachian population). During 2009-2011, there were 6,739 live births and 258 failed screening tests for a 3.8% failure rate at the University of Kentucky. We will also recruit children who fail newborn hearing screens that are born in other regional hospitals but are referred to our clinic for outpatient testing. Our institution has the highest volume of follow-up infant diagnostic tests after a failed screening test for our region. During 2009- 2011 26,296 live births occurred in hospitals within a 50-mile radius of Lexington with a total of 626 failed newborn hearing screens (2.4% failure rate).

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1. Background:

Pediatric hearing loss is the most common neonatal sensory disorder in the United States with an incidence of approximately 1 per 1000 births. The sense of hearing is vital during the early years of life for the development of speech, language, and cognition. Deafness in early childhood can result in lifelong learning delay and disability; however, early identification and intervention can prevent educational and social consequences. Universal newborn hearing screening programs in hospitals have been implemented in most states, including Kentucky, and help in early identification and timely intervention for children born with hearing loss; however, newborn hearing screening is a significant undertaking. This screening does not involve simple blood work, but involves the use of an objective electrophysiological evaluation of the auditory system through the use of an automated auditory brainstem response (AABR) and/or the evoked otoacoustic emissions (OAE) measures. Newborns that fail their hearing screening or high-risk children undergo an audiological diagnostic assessment following discharge and depending on the tests results may have serial assessments with subsequent appropriate intervention. Intervention may include fitting with hearing aids or possibly cochlear implantation. Although high-risk children may undergo periodic audiological assessment, issues such as compliance, socioeconomic factors, and access to care remain major barriers to early identification and subsequent intervention. The consequences of delayed diagnosis and/or failure for appropriate intervention for infants with hearing loss can be significant delay in language, cognitive, and social development. This may lead to adulthood challenges in education and employment. In order to identify newborn hearing loss, hearing screening has become a mandatory component of post-natal care for infants. Mandatory newborn hearing has been recommended by the National Institutes of Health, Joint Committee on Infant Hearing (JCIH), and the American Academy of Pediatrics. The JCIH has established the gold standard of infant screening, follow-up, and intervention and serves as the standard for this study. 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 lab 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. We are also 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 are delayed in their follow-up. 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

2. Objectives:

Hypothesis: The assistance of a patient navigator for families with a newborn who failed a newborn hearing-screening test will result in improved patient compliance, patient satisfaction, and age of diagnosis and intervention of pediatric hearing loss.

Specific Aim 1: Examine the effect of a patient navigator to influence the age of diagnosis and intervention for pediatric hearing loss.

Specific Aim 2: Examine the effect of a patient navigator to influence patient satisfaction, knowledge, and compliance with the hearing evaluation and intervention process following newborn hearing screening.

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3. Study Design:

For Specific Aim 1, mothers of newborns failing birth hearing screening will be recruited. Participants will be placed into Appalachian and non-Appalachian stratum and then randomized into a patient navigator group or the standard of care group. The navigator group will receive an intervention consisting of educational support from a patient navigator. We will compare the non-adherence rates to obtain the recommended testing within 3 months between groups and strata. The timing of testing will also be assessed and compared between regional strata. At enrollment, we will collect data on maternal socioeconomic status, educational level, and distance from testing center and infant health. Findings will be correlated with adherence to follow-up and timing of services. If the child receives follow up before 3 months and it is determined that child has hearing loss he or she will be approached by a research staff member to participate in the second part of the study (Aim 2) to be randomized and either followed for one year by the patient navigator or to follow standard of care practice.

For Specific Aim 2, mothers of newborns will also be recruited and randomized to navigator vs. no navigator, but this Aim focuses on the diagnosis of hearing loss after the child has had two failed outpatient audiological tests. At the time of hearing loss diagnosis, these participants will be stratified and then randomized similar to Aim 1 into trial arms. Patients will be randomized into 2 groups. Group 1 will have contact with the navigator from the time of hearing loss diagnosis until the first year of life while group 2 will not have the navigator (STANDARD PRACTICE).

4. Study Population and Subject Recruitment Methods and Privacy:

Specific Aim 1: This portion of the study will involve infants born at the University of Kentucky Medical Center, infants born at outside facilities and their families (that are referred to UKMC Audiology Clinic for follow-up testing), and infants and families that are referred to the Commission for Children with Special Health Care Needs (CCSHCN) for follow-up testing. Children that are born at UK undergo newborn hearing screening using a test called ALGO. This test is performed on infants who are older than 34 weeks gestation, have normal external ear, are not on any stimulants, and are in a sleeping or relaxed state approximately 24 hours after birth. This is an automated test that is performed as standard of practice and the results of the test are listed as "PASS" or "REFER." When a child has a "REFER" result then the postpartum nurses or clerk calls the UK ENT clinic (the office of the PI) prior to discharge from the hospital for scheduling a diagnostic hearing test as standard practice. At that point, the PI is an authorized care provider for the patient and that is how the subjects are identified.

The subjects who have a child born at UKMC are approached by a study representative, who physically goes to the patient's hospital room at UKMC to discuss the study. The parents of the child with a failed hearing test will be given a letter (**see attached**) regarding the research project at the time the results are communicated and will be notified that a member of the research team will contact them regarding the study. Once this phone call is made to the PI's office, a member of the research staff will go to the inpatient room in the postpartum ward of UKMC to discuss the study and go over the informed consent/HIPAA documents. If they decline to be in the study then they will tell the study representative at the time that they present the study in the hospital room and they will not be contacted further. They will be verbally reassured that their participation or lack thereof will have no bearing on their or their child's care.

The subjects who are discharged at other facilities will receive telephone contact by the research team once the hospital staff contacts the UK Otolaryngology Clinic for outpatient testing follow up. The CCSHCN staff will also contact the UK research team when a potentially eligible subject has an appointment with them for outpatient follow up testing. The research team will contact potential subjects to confirm their outpatient appointment at their hearing healthcare clinic, providing customer service to patients and providing a secondary understanding of appointment dates and times. At that point, the mothers will be asked if they would like to participate in a research study regarding patient navigation

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and be given study details by phone and have opportunity to ask questions. The mothers will be consented by phone (see verbal consent form). If they decline to be in the study then they will tell the study staff member at the time that they present the study by phone and they will not be contacted further. They will be verbally reassured that their participation or lack thereof will have no bearing on their or their child's care.

For either group in Aim 1 there will be no discrimination on age, gender, or ethnicity; however, the parents must be able to speak English or Spanish, as that will be the primary means of communicating with the patient navigator. We expect to enroll approximately 284 subjects in this portion of the study (enrollment should last about 2 years).

Inclusion criteria:

1. Identify parents of children who are born at UKMC in the postpartum ward following mandatory newborn hearing screening, or parents whose children are receiving follow up testing (due to referral after mandatory newborn hearing screening) at UK Audiology or the Commission for Children with Special Health Care Needs
2. Children must be born after 34 weeks gestation
3. Newborns fail hearing screening in one or both ears
4. Parents are willing to have definitive hearing testing performed
5. Parents are willing to be contacted by study coordinators and/or navigator to monitor progress and testing outcomes
6. Parents must be able to speak English or Spanish as the navigator will be speaking one of these languages and this will be the primary means of communication over the phone.

Exclusion criteria:

1. Children who pass their newborn hearing screen
2. Children who are hospitalized past 30 days after birth or who are born prior to 34 weeks gestation
3. Children and parents live outside Kentucky or who will be moving out of Kentucky within the first year of life.
4. Children in the NICU for an extended period of time (they often are delayed in getting their ALGO and subsequent testing)

Specific Aim 2: This segment of the study is evaluating all participants from Aim 1 who fail the follow up outpatient hearing test. This Aim may recruit additional subjects who fail newborn hearing tests from outside hospitals, who are following up for further hearing testing and diagnosed with hearing loss. During study Aim 2, a child is seen once in the Audiology clinic for outpatient follow up hearing testing. Once the child fails the first test, he or she will return for testing with another audiologist to confirm hearing loss. At that point, the research team will be notified that child has met criteria for the second part of the study and parent(s) will be approached with information about the study or will be contacted by phone after the appointment by research staff who will discuss the study and obtain verbal consent and sign consent or provide verbal if they choose to participate.

The parents will be verbally reassured that their participation or lack thereof will have no bearing on their or their child's care. The children who enroll in Aim 2 must meet the same inclusion criteria as Aim 1, except they also must be younger than 6 months old and have a final diagnosis of hearing loss. We expect to enroll 62 subjects, with 31 children from the Aim 1 enrollment and 31 from identified clinic patients who are seen in the Audiology clinic for follow up hearing tests. For this Aim there again will be no discrimination on age, gender, or ethnicity; however, the parents must be able to speak English or Spanish, as that will be the primary means of communicating with the patient navigator.

Patients who previously received navigation in Aim 1 will also be approached by a research staff member after a hearing loss diagnosis is given. These patients will also be consented again for Aim

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2 of the study, but they will continue to receive navigation instead of being randomized a second time. This group of patients will also be followed in the study for 12 months.

5. Informed Consent Process:

Aim 1: At the time of the failed ALGO test, the nurse administering the test will give an information letter to the parents of the child who fails the newborn hearing test. As standard practice, the newborn nursery staff calls our clinic to schedule diagnostic hearing testing. That is how a prospective research subject is identified. At that time our research staff will go to the patient room to talk with the parents about the study. A member of the research staff who is authorized to obtain consent will come to inpatient hospital room to discuss the study and obtain consent.

Subjects who have a child who failed the newborn hearing in another facility will be contacted by phone once they have an outpatient hearing screening test (ABR) scheduled. They will have an informed consent by phone through a member of the research staff and will have opportunity to discuss study and ask questions.

Aim 2: At the time of the initial clinic visit for follow up hearing testing, parent(s) of a child who is found to have hearing loss will be approached by research staff who is authorized to obtain informed consent to discuss the study and obtain consent or will be contacted by phone after appointment by research staff who will discuss the study and obtain verbal consent. The parent(s) who signed the consent for the Aim 1 portion of the study and have a child with a final diagnosis of hearing loss through two different ABRs by two different audiologists will be re-consented in the clinic after diagnosis or verbally consented by phone to the current informed consents of the study portion that randomizes to navigation vs. no navigation. Children who were also born in an outside of UK institution, but are followed up with additional outpatient testing with a hearing loss diagnosis are also included.

6. Research Procedures:

Specific Aim 1: The same outcomes will be measured in both groups. Group 1 will be contacted every 2 weeks after discharge from the hospital regarding their child who failed the newborn hearing screen by the patient navigator. This contact will primarily occur through phone calls, but can also occur through email or text messages on a password protected phone if the patient prefers one of these communication methods. Communications between the patient and patient navigator will consist of inquiring on the health and development of the child, addressing questions about hearing, hearing loss, upcoming tests, and intervention services. The navigator will attempt to have these questions answered by clinical staff involved in the patients care and will communicate this to the family. Group 2 will not have navigator contact but will work directly with their hearing healthcare clinic and other referral centers for diagnostic and intervention services (THIS IS THE CURRENT STANDARD OF PRACTICE). Parents in each group of the children born at UKMC, children born at outside facilities (and referred to UKMC Audiology clinic for follow up testing), and children referred to CSHCN for follow up testing will be given a standard brochure that contains basic information about newborn hearing screening and a contact number regarding obtaining further assistance with the diagnostic testing and/or treatment. This is document produced and circulated by the state of Kentucky childhood early hearing detection and intervention agency (SEE APPENDIX 1). At the time of enrollment, parents of the child with the failed hearing screening will fill out a questionnaire which assesses patient satisfaction, knowledge, attitudes, and behaviors, along with some demographic information (**see attached**) from both groups. The subjects who are discharged from outside facilities will have the questionnaire completed by mail, email (through REDCap), or phone with the research staff member. Notes from phone conversations from navigator phone calls will be recorded by the navigator and then recorded on an excel spreadsheet. The data from the questionnaire and the other time points will also be recorded on an excel spreadsheet. At the follow up appointment the research team will also collect data on the outcome of the diagnostic testing. If subjects do not receive their diagnostic follow up within the 3 month time frame

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a member of the research team will contact them by phone in order to complete the exit questionnaire and determine if they had diagnostic follow-up at another facility. If the patient cannot be reached by phone the UK research team will work collaboratively with CSHCN to find out (through the EHDI system) if these patients received follow up care in another clinic outside of the study or if they were lost to follow up. This data will be kept in a password-protected file on a password-protected computer and along with the consents will be kept in the locked office of the PI. This data will be kept for a total of 6 years after the conclusion of the study.

Specific Aim 2: The same outcomes will be measured in both groups, but this Aim will focus on the timing of intervention from the hearing screening as an outpatient. The patients randomized to the navigator group will be contacted weekly-biweekly to provide educational and psychosocial support of participants with the same four conversation points from Aim 1. The testing that diagnosed hearing loss will be recorded into the EHDI database. At the time of enrollment, parents of the child with the failed hearing test will also fill out a questionnaire which assesses patient satisfaction, knowledge, attitudes, and behaviors, along with some demographic information (**see attached**) from both groups (navigator and non-navigator). We will have the patients complete the questionnaire at enrollment and 12 months after enrollment. We will also record the age of initial diagnostic test at their hearing healthcare clinic (depending on where the patient received diagnostic testing), age of definitive diagnosis of hearing loss, age of early intervention consultation, age of hearing aid fitting, and (if patient meets criteria for cochlear implantation) age of cochlear implantation. Parent(s) of children in this Aim will also receive another questionnaire, similar to the one they receive at the beginning of Aim 2 that assesses patient satisfaction, knowledge, attitudes and behaviors with follow up demographic information during the one year follow up. Notes from phone conversations from navigator phone calls and data from the questionnaire and at the other time points will be recorded by the navigator and then recorded on an excel spreadsheet. This data also will be kept in a password-protected file on a password-protected computer and along with the consents will be kept in the locked office of the PI. This data also will be kept for a total of 6 years after the conclusion of the study.

7. Resources:

The study does not require any special space. A patient navigator is not a care provider but is 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.

8. Potential Risks and Safety Precautions:

The challenges present in this study relate to the Belmont report issues of respect for persons, beneficence, and justice. The respect for persons becomes an issue in that we are studying children and they are naturally a vulnerable population. A major concern in diagnosing and managing children with hearing loss is that they are lost to follow-up after they leave the hospital. In order to gain access to these children, we need to recruit them while they are in the hospital and approaching them about the study may produce pressure to participate. There is a risk of coercion in this setting. To prevent this coercion, the PI (who could potentially be involved in the patient's care) will not consent the patient or have contact with the patient's family during study Aim 1. The issue of beneficence also comes when dealing with children with hearing loss. If there is miscommunication or misunderstanding of the parents about the information presented or mistrust of the navigator or research team, then this may lead the family further away from the appropriate diagnostic and treatment resources. There are natural safeguards against this as the state of Kentucky monitors failed newborn hearing screening and

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independently and families are contacted by the state until they are seen in follow-up. There is also a risk of breach of confidentiality, as we will be contacting this family and interacting with other hearing professionals involved in the care of the child with hearing loss.

When recruiting these patients we will need to be very careful not to be coercive. Parents when they've found out that their child failed a newborn hearing screen may be very susceptible to coercion. The nursery staff will be the first contact, not to discuss the study, but to ask the parents if they'd be willing for the research staff to talk with them about the study. If they say no then they will be ensured that they be provided the standard care as is routine when a child fails a newborn hearing screen. If they agree to participate then the research coordinator will go to the hospital room and meet personally with that family and explain the study. He or she will also become a part of the care team in contacting potential subjects who have children born at outside facilities by confirming appointment times and thereby helping the families in providing appropriate patient service. In asking potential subjects if they would like to participate in the navigator study, the coordinator will not be coercive in his or her approach, but will only give further information if the potential subjects would like more informed knowledge about the study. The coordinator is not a healthcare provider and will not be involved in providing care thus will reduce the pressure of coercion in patients. The navigator will be trained carefully to assist patients, answer their questions, and guide them through the diagnostic and therapeutic process of childhood hearing loss. In order to prevent miscommunication, they will not be allowed to provide medical advice but facilitate their contact with their healthcare providers.

During study Aim 2, child is seen once in the Audiology clinic for outpatient follow up hearing testing. Once the child fails the first test, he or she will return for testing with another audiologist to confirm hearing loss. At that point, a member of the research staff, will be notified that child has met criteria for the second part of the study and parent(s) will be approached or called with information about study and given a consent in-person or will be offered to receive a mailed consent form when called. PI may treat child during the course of the Aim 2 study, but this will be after parent has decided to either participate or decline study.

The charts and research records of these patients will be kept in the locked office of the PI at all times and any electronic files will be kept on the password protected desktop computer of the PI. Only the research staff will have access to the research data and all will have human subject protection training.

9. Benefit vs. Risk:

The potential benefit of participation in both Aim 1 and Aim 2 of this research is the early detection and intervention of hearing loss in children and to improve community and regional awareness of hearing loss in children. The risks include potential compromise of patient confidentiality; however, measures as described above will be taken to maintain confidentiality.

10. Available Alternative 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.

11. Research Materials, Records, and Privacy:

The data, consents, and questionnaires will be kept in the locked office of the PI. These materials will be retained during the study and 6 years after the study.

Verbal Consent Form for Telephone Enrollment and Survey
The Role of a Patient Navigator in Early Pediatric Hearing Loss
Identification and Intervention

Hello, my name is_____. I am calling on behalf of the Commission for Children with Special Health Care Needs. May I speak with the parent/guardian of (child's name)_____? Your child has a follow-up appointment with the CSHCN Audiology Clinic on (date of appointment)_____. This appointment is for a follow-up hearing test, because your child had an abnormal hearing screening in the hospital.

I am a member of a collaborative research team between the Commission and the University of Kentucky. We are working together on a study to learn about the barriers families face in receiving hearing healthcare. We are looking for individuals who might be interested in participating in our study. Would you be interested in hearing more about this study?

I'd first like to determine if you are eligible based on a few questions: 1) was your child in the NICU for an extended period of time (more than 10 days), 2) was your child born premature (before 34 weeks gestation), 3) did your child fail the newborn hearing screening in one or both ears, 4) are you at least 18 years old, 5) are you planning on living in Kentucky for at least the next 12 months, 6) are you willing to have your child's hearing tested further, 7) are you will to have further testing performed at a clinic in the state of Kentucky, 8) can you speak and read English or Spanish, and 9) are you willing to be contacted by our study team?

The Commission for Children with Special Health Care Needs in partnership with The University of Kentucky Department of Otolaryngology – Head and Neck Surgery (Ear, Nose and Throat) is inviting you to participate in a research study because your child had an abnormal Newborn Hearing Screening while in the hospital and he or she has a follow up hearing test at the Commission for Children with Special Health Care Needs Audiology Clinic. By doing this study, we would like to find if a patient navigator or standard of care is more helpful in assisting families in getting access to hearing services. You may not get any direct benefit from participating in this study, but your participation may help doctors better understand and/or treat others who have your child's condition in the future.

The person in charge of this study is Dr. Matthew Bush, the Principal Investigator, or PI. If you decide to participate, you will be one of about 284 people to participate in this collaborative study between the CSHCN and the University of Kentucky.

We want to learn from you about the barriers for getting hearing healthcare services for patients. You may be in a group who receives standard of care treatment only (or health services that you would receive if you were not participating in the study) or in a group who works with a patient navigator by phone and receives standard of care treatment. A patient navigator is a trained person who has experience and interest in child hearing health and his or her role is to help families get appropriate services and access to resources for their child. We want to see which way is more helpful in understanding your child's condition and allow for easier access to follow up services.

Research procedures will take place over the phone and at the CCSHCN Audiology Clinic. The study will last for about 3 months. If you agree to participate over the phone today, you will then complete a survey that will last for about 15 minutes. After the survey, you will be randomized to be in the patient navigator group or be in the standard of care treatment only group. Randomization is like flipping a coin, you, your healthcare team or the person consenting you over the phone will not get to choose the group in which you will participate. You will also be asked to verify your contact information.

If you are randomized to be in the navigator group, you will receive a weekly/bi-weekly phone call from the navigator to discuss the hearing of your child and his or her progress until your child has his or her hearing testing in the CCSHCN Audiology Clinic. If you are in the standard of care only group, you will not have any further contact by phone until follow up is completed. Families in both groups will have a follow up survey that will take about 15 minutes when they return to the CCSHCN Audiology Clinic. The second survey may also be completed over the phone with one of the members of our research team. After completion of the follow up survey, you will be mailed a \$20 check for your time. We will monitor your child's health through the duration of the study. This includes: demographic information, results of physical exams, hearing tests, and other diagnostic and medical procedures as well as medical and social history.

The potential risk to participating in the study is the chance of your confidential information being seen by those not involved in the study. We will give you and your child a single study number that will be linked to you and your child's identifying information, but we will take every precaution to ensure your and your child's information is protected and kept confidential. Only personnel working on the study have access to study information and it is kept on a password protected computer in a locked office. The information that you give will be grouped with information from other participants and not identified with you or your child personally. We do use a computer-based tool called REDCap to store information from the surveys entered by study personnel. The surveys entered do not have any identifying information that is entered into the computer.

If you earn \$600 or more by participating in any research, it is potentially reportable for tax purposes..

Your participation in this study is voluntary and at any time during the study you can stop participating and still keep the benefits and rights you had prior to participation. If you decide that you do not want to participate, the choice is to receive standard of care follow up for your child's condition.

There is no cost to you for participation other than a small amount of time spent on the phone if you are in the navigator group and to complete the surveys. You will be contacted by phone by the navigator unless you have any questions, you will be given a contact number to call. If you have further questions about the study we will give you Dr. Matthew Bush's contact number at (859) 257-5097 and the research office contact at (859) 218-2167.

Do you have any further questions?
Do you consent to participate in this study?

Participant's Name

Date of Consent

Name of Authorized Person to Obtain
Informed Consent

Date of Consent

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As mentioned above, all data and documents will be kept in the locked office of the PI at all times. 6 years after the conclusion of the study, the data will be deleted from the computer and erased. 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.

13. Payment:

Subjects will be given a \$10 gift card or check for completing the initial questionnaire and \$10 gift card or check for completing the exit questionnaire after enrolling in Aim 1 of the research. The subjects who will enroll and receive the entrance questionnaire by mail, email, or phone and exit questionnaire when they follow up in the UK Audiology Clinic or the CSHCN Clinic in Aim 1 will receive both gift cards in person at that time or checks in the mail. If subject does not follow up for testing in the UK Audiology Clinic or the CSHCN Clinic, a \$10 check will be mailed to subject upon receipt of initial questionnaire.

No payment is given for Aim 2.

14. Costs to Subjects:

There is no cost to patients for involvement in this research.

17. Data and Safety Monitoring: N/A**18. Subject Complaints:**

Patients and families that are involved may contact the navigator, PI and/or their primary care and/or referring physician if they experience any concerns with the research or if they would like to withdraw their participation from the study. Additionally, they may contact ORI Research Compliance Officer's toll-free phone number (1-866-400-9428) as a subject's primary contact point.

19. Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture: N/A**20. HIV/AIDS Research:** N/A**21. PI-Sponsored FDA-Regulated Research:** N/A