# Clinical Study of the Iowa Cochlear Implant Clinical Research Center Hybrid L24 and Standard Cochlear Implants in Profoundly Deaf Infants: Protocol

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## ATTACHMENT 3
## Investigational Protocol: Iowa Cochlear Implant Clinical Research Center Hybrid L24 and Standard Cochlear Implants in Profoundly Deaf Infants

### 1 INVESTIGATIONAL PROTOCOL

The purpose of this feasibility study is to evaluate whether a Nucleus L24 and a FDA approved standard-length device in the contralateral ear can provide useful binaural hearing in pediatric subjects who have bilateral profound hearing loss, meeting the criteria for cochlear implantation. Unlike a conventional cochlear implant, the Nucleus L24 is designed to preserve the regions of the cochlear partition that are apical to the electrode, thus leaving them available for possible future advances in the field of otolaryngology and hearing devices, such as mammalian hair cell regeneration techniques or improved implantable hearing devices. The Nucleus L24 (16 mm) array stimulates the basal turn of the cochlea, in an attempt to preserve the middle and apical regions of the scala media.

Criterion for selection of the Nucleus L24 and a standard-length device group will be parent interest in bilateral implantation and the following criteria: profound bilateral sensorineural hearing loss; lack of benefit from appropriately fit binaural hearing aids worn on a full-time basis; language deficit; and supportive family dynamics. Qualified participants must also meet the following criteria for inclusion and exclusion, respectively.

#### 1.1 Criteria for Inclusion:

1. Twelve to twenty-four months of age at the time of implantation.
2. Audiometric thresholds for frequencies 250 to 8000 Hz in the profound hearing range bilaterally. The type of hearing loss must be categorized as sensorineural in nature.
3. English spoken as a primary language (mono-lingual English-speaking family, where English is the primary language).
4. Willingness to comply with all study requirements.
5. Minimum of three-month hearing aid trial with appropriately fit hearing aids.
6. Patent cochlea and normal cochlear anatomy as shown by a CT scan. It is standard clinical practice to perform a CT scan on any patient pursuing cochlear implantation.

#### 1.2 Criteria for Exclusion:

1. Medical or psychological conditions that contraindicate undergoing surgery.
2. Ossification or any other cochlear anomaly that might prevent complete insertion of the electrode array.
3. Developmental disabilities or other conditions that would prevent or restrict participation in the audiological evaluations and clinical trial.
4. Hearing loss of neural or central origin.
5. Unrealistic expectations on the part of the candidate and/or candidate's family, regarding the possible benefits, risks, and limitations that are inherent to the surgical procedure(s) and prosthetic devices.

6. Unwillingness or inability of the candidate to comply with all investigational requirements.
7. Active middle ear infection.

## 1.3 Investigational Procedure

### *1.3.1 Design Overview:*

The study will be conducted as a repeated-measure, single-subject experiment. A single-subject research design (in which each participant serves as his or her own control) is appropriate because it accommodates the heterogeneity that characterizes hearing-impaired populations. Blinding or masking procedures are not included in the design, as it is not possible to conceal the presence or absence of a cochlear implant from device recipients and/or clinical investigators.

Preoperatively, candidates will be assessed with their current amplification to evaluate their appropriateness for entrance into the study. The candidates' audiometric configuration must meet the above inclusion criteria. That is, the candidate must have a profound sensorineural hearing loss from 250 to 8000 Hz. Prior to testing, the appropriateness of the hearing aid fitting will be assessed and adjustments made if necessary. In cases where amplification has not been used for more than one year, new hearing aids will be fit, worn for a minimum three-month trial and the participants re-evaluated to confirm continuance with the study.

Fifteen infants will receive one Nucleus L24 array and a FDA approved standard-length array on contralateral ears. We will alternate every other subject between the right and left ears as to which ear gets the Nucleus L24. Postoperatively, the right ear only, left ear only, and the bilateral listening modes will be compared with repeated testing through five years of age of the child. These comparisons will help to evaluate the effects of bilateral stimulation using a shorter electrode cochlear implant to possibly preserve the scala media, organ of Corti, and supporting cells for future medical interventions and a standard length implant on the contralateral ear. In addition, we will attempt to compare speech perception and speech/language measure results with age-matched children implanted with standard-length bilateral devices. The following defines the various modes referenced throughout the course of this text:

### *1.3.2 Device Description:*

The following defines the various modes referenced throughout the course of this text:

**Nucleus L24 Electrode Array:** The Nucleus Hybrid L24 cochlear implant incorporates an electrode array designed to preserve residual hearing. This has been accomplished by employing a thin, straight, intracochlear electrode array attached to a Nucleus cochlear implant receiver/stimulator (the same as currently used in the approved Nucleus Freedom™ cochlear implant system P970051/S028). The Nucleus Hybrid L24 array has 22 electrodes spread over 16 mm and an anticipated insertion depth of 16 mm. It is slim, with its dimensions ranging from 0.35 x 0.25 mm (at the tip) to 0.55 x 0.4 mm, and designed to minimize lateral wall forces with a stiffened basal section to prevent buckling. A winglet is attached to the electrode lead to allow a better handling of the electrode array and to avoid over insertion. The electrode array also incorporates a collar to prevent over-insertion, or further migration, into the cochlea. The resultant insertion angle is about 280-300° in the scala tympani for the Hybrid L24, as confirmed in temporal bone trials at the Medical University Hannover and the University of Melbourne, compared with an insertion angle of 450° for the Nucleus Contour Advance.

The Nucleus Hybrid L24 is the same device described in IDE No. G070191. See ATTACHMENT 1 for a letter from the Sponsor of IDE No. G070191 authorizing the FDA to review the information in IDE No. G070191 for purposes of the current IDE application. The Nucleus Hybrid L24 electrode array also incorporates a platinum ring immediately proximal to the collar. The ring is positioned such that it is located at the site of entry after insertion of the array into the cochlea. The platinum ring is intended to encourage tissue growth to promote sealing of the entry into the cochlea after insertion, and to fixate the array, at the site of entry, so that it does not migrate into or out of the cochlea once inserted.

**FDA Approved Standard-Length Electrode Array:** The standard electrode array.

**Bilateral Stimulation**: The use of the right and left ear devices together.

### 1.4 Preoperative Procedures:

#### *1.4.1 Informed Consent:*

A preoperative interview will be conducted by the surgeon and audiologist to inform the parent(s) or legal guardian of the child about all aspects of implantation with the Nucleus L24 cochlear implant, study expectations, number of visits, surgical procedure, as well as the postoperative evaluation schedule. The risks of surgery shall be explained to the parent(s) or guardian as outlined on the Informed Consent Form (Parental Agreement). These include the normal risks associated with general anesthetic, as well as other risks such as facial paralysis, dizziness, meningitis, postoperative discomfort, and skin flap complications. The potential limitations and advantages of implantation with the Nucleus Nucleus L24 cochlear implant shall also be explained. The parent(s) or guardian will be given adequate time to review the Informed Consent Form and given the opportunity to ask questions about the document itself and/or the study prior to signing the Informed Consent Form. The parent(s) or guardian will then be given a copy of the signed Informed Consent Form.

***Note that the Informed Consent Form must be reviewed and signed by the relevant parties prior to any study evaluation taking place. Any testing, for screening purposes, completed prior to consent being obtained must be repeated after the participant consents to participation in the study.***

#### *1.4.2 Hearing History:*

Information regarding participant's hearing-history (etiology, onset of hearing loss, duration of profound hearing loss, amplification use) is to be reported.

#### *1.4.3 Medical/Surgical History:*

The participant's medical/surgical history is to be reported and is required in order to determine that the participant is medically suitable for cochlear implantation. Information to be collected may include: the participant's general medical history, medications, radiological information (i.e. x-rays), otologic history, and otologic surgical history.

#### *1.4.4 Fitting of Hearing Aids:*

Lack of benefit from appropriately fit hearing aids will be determined by the lack of progress in the development of simple auditory skills as defined by aided and unaided behavioral thresholds; auditory brainstem response testing; otoacoustic emission testing; steady state evoked potential testing; IT-MAIS and/or the lack of developmentally appropriate vocal behaviors. Criteria for appropriate vocal behaviors include achieving the production of canonical babble as defined by production of reduplicated sequences

such as [mamama], [dadadal, or [bababal] (Oller and Eilers 1988). Hearing aid use will be determined by parental and educator reports.

Bilateral behind-the-ear (BTE) hearing aids will be used during the three-month trial period. Audiometric criteria must be met with the participants using appropriately fit hearing aids. If the participant has not been appropriately fit with amplification, hearing aids will be fit prior to the completion of aided audiometric testing to ensure that candidacy criteria are met.

The Desired Sensation Level (DSL) hearing aid fitting strategy will be used (Seewald, 1995) to assess the degree to which real-ear or coupler-predicted targets are met for each patient. These fitting methods are based on extensive research and clinical trials with patients with sensorineural hearing loss and are the most widely used fitting formulas in clinical use.

To be considered appropriately fit, the slope of the frequency response from real-ear measures or DSL measures of the hearing aid must be within the target specified by the Audioscan Verifit System. If this can not be accomplished with the subject's hearing aids, replacement hearing aids will be used.

For those candidates that wear hearing aids fit based on DSL targets, coupler-predicted maximum output levels at 90 dB HL will not be exceeded.

It is recognized that prescriptive methods are based on average requirements, and that individuals may find deviations from target values optimal for sound loudness, quality, or clarity. For example, individual adjustments required to relieve occlusion effects will be permitted.

### *1.4.5 Audiological Assessment*

The degree of hearing loss will be determined by a combination of electrophysiological and behavioral tests including auditory brainstem response testing; otoacoustic emission testing; steady state evoked potential testing; behavioral observation audiometry, visual reinforcement audiometry and/or conditioned play audiometry. Audiological assessment will include unaided and aided audiometric thresholds.

Unaided audiometric thresholds will be obtained for each ear, using insert earphones when possible. Thresholds will also be obtained using conditioned play audiometric (CPA) techniques, visual reinforcement audiometric (VRA) and/or behavioral observation (BOA) techniques for pure-tone air-conduction. The most appropriate testing technique will be used according to the child's age. Bone conduction testing will be completed using the above techniques. Aided audiometric thresholds will be obtained, using narrowband noise, for each ear in the sound-field using standard audiometric techniques, CPA, VRA or BOA with the speakers positioned at 45°-azimuth relative to the participant's head. Results for unaided testing must be reported for the frequencies of 250, 500, 1000, 2000, 4000, 6000, and 8000 Hz. Results for aided testing needs to be reported for the frequencies of 250, 500, 1000, 2000 and 4000 Hz.

A candidate is only considered enrolled when 1) a properly executed informed consent form has been completed and returned, 2) his/her preoperative candidacy evaluation is accepted, and 3) both forms have been reviewed and approved by the University of Iowa.

### *1.4.6 Baseline Speech Perception and Speech/Language Testing*

In order to establish a baseline level of auditory function, auditory function will be evaluated in the best aided condition using the following battery of speech language production and subjective measures:

- The Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) Zimmerman-Phillips, Osberger, & Robbins, 1997) is a parent questionnaire that consists of ten questions regarding a young infant or toddler's auditory behavior, e.g. "Does the child spontaneously respond to his/her name in quiet with auditory cues?" Each question is scored on a five point scale: 0=never, 1=rarely, 2=occasionally, 3=frequently, and 4=always. The aim of this tool is to assess the benefit of the child's personal amplification device(s). This questionnaire is generally used during the cochlear implant work-up to assess hearing aid benefit. It is also used post-cochlear implantation to chart the progress the child is making with his/her cochlear implant when other formalized speech perception tests are not appropriate.
- Vocalizations/speech sample protocol: The samples will be elicited by presenting the child with a set of age-appropriate toys with lexical labels that have phonemes representing early consonant productions and the entire vowel quadrilateral.
- *MacArthur Communicative Developmental Inventories (CDI)* and the *Minnesota Child Development Inventory* (*MinnCDI,* Ireton & Thwing, 1974) are parent report measures that provide an index of growth from birth to 30 months of age. The *CDI* has a ceiling on the *Words and Sentences* version of 30 months of age; however the *MinnCDI* assesses development up to 6 years of age. The *CDI* also has two forms: *Gestures and Words* for infants aged 8- to 16-months-old and *Words and Sentences* for children aged 17- to 30-months-old.
- The *Preschool Language Scale-3* (PLS-3) (Zimmerman, Steiner, & Pond 1992) is a standardized language test that is used to measure the language development of children with normal hearing aged 0 months to 83 months. The test evaluates "Expressive Communication" and "Auditory Comprehension" and is designed to evaluate skills in a variety of areas: vocal development, social communication, attention, semantics (content), structure (form), and integrative thinking skills.

### *1.4.7 Surgical Procedure:*

The surgical procedure for the Nucleus L24 cochlear implant requires care to prevent inner ear damage. The cochleostomy is 0.8 mm in diameter for the Nucleus L24 while the cochleostomy for the standard implant will be 1.0 to 1.2 mm in diameter. The cochleostomy will be made in a similar position for both devices. Creation of the cochleostomy requires control of bleeding and removal of bone over the scala tympany exposing the endosteum. The endosteum is removed with a 0.2 mm hook. No suctioning of perilymph is allowed. Soft surgery techniques with slow advancement will be used for both implantations attempting to be as atraumatic as possible. For the Nucleus L24 cochlear implant, the array is inserted 16 mm into the scala tympani.

The most important tenets for implantation of the L24 are given below.

1. A complete mastoidectomy with preservation of the cortex in the area of the tegmen mastoideum performed. Completion of exposure, bony work, and soft tissue work before

completing the cochleostomy. This includes drilling a seat for the electronic package, harvesting and constructing a temporal fascia washer. The facial recess or posterior tympanotomy must be opened to allow complete visualization of the round window. The overhanging niche of the round window must be removed using a diamond burr completely exposing the entire round window membrane. These steps minimize the open cochlea's exposure to blood and bone dust. A suture is placed through the boney over hang at the tegmen mastoideum to secure the electrode lead prior to placing the electrode in the scala tympani. This suture stabilizes the springy lead of the implant and prevents translational movement in the scala tympani as the electrode is advanced.

2. Minimally traumatic cochleostomy. A strategy similar to that used to perform a 'drill-out' stapedectomy. This includes making sure bleeding is controlled, bone is slowly removed over the area of the cochleostomy leaving the endosteum of the inner ear intact, and not using suction in the area of an open inner ear. The cochleostomy must be placed approximately 1 mm anterior and inferior to the floor attachment of the round window membrane. The promontory of the cochlea in this portion can be more than 1 mm thick. It is suggested that the promontory be saucerized in this region with a 1-mm diamond burr. Placement of the cochleostomy in the anterior-inferior position to the round window membrane avoids damage to the scala media and spiral ligament. The burr should not enter the scala tympani. The endosteum is opened with a 0.2-mm footplate hook. The smallest cochleostomy needed to insert the implant is made (0.7–0.8 mm). No suctioning of the perilymph is permitted.

3. Minimally traumatic insertion. Short lapse of time between opening the cochlea and insertion is emphasized. The electrode is stabilized with a suture at the lateral tegmen mastoid cortex prior to insertion into the cochlea. Actual insertion of the electrode is slow (30–45 s) to minimize intracochlear trauma. The fascia washer seals the cochleostomy. No further packing in the scala tympani is allowed.

***Intraoperative impedance telemetry measurements will be performed using CG, MP1, MP2 and MP1+2 modes.*** The postoperative hospital stay is usually <23 hours.

### 1.5 Postoperative Procedures:

#### *1.5.1 Device Activation*

The participants will be fit with a Nucleus CP810 sound processor in the ear implanted with a L24 device. Speech processing strategies used with this device will include ACE (RE), ACE, CIS (RE), CIS or SPEAK, which are all FDA approved for children. Threshold (T) and comfort (C) values will be measured for the electrical stimulation for each of the channels (22 on the Nucleus L24 cochlear implant). Impedance telemetry results using common ground (CG) and monopolar (MP1, MP2 and MP1+2) stimulation modes will also be recorded. This information will be used to program the speech processor and also to monitor the device for possible degradation of function and/or damage to neural elements.

The process of adjusting the speech processor programs takes place over a period of several months for young children. Techniques used for programming speech processors of young children are standard audiological techniques for children in this age group and require two audiologists to perform. Play audiometry techniques will be used, as appropriate for the child's developmental level, to determine electrical threshold levels for the channels in a child's program. Behavioral observation or visual reinforcement audiometry will be used for children who are unable to perform play audiometry. Electrophysiological data will verify levels obtained behaviorally or in those

instances when behavioral information is limited. Electrical comfort levels will be set conservatively on initial programs to ensure a comfortable listening level for the child. Levels will be increased gradually at home and over several programming sessions during the first year of implant use. This approach is necessary in order to ensure comfortable listening levels are not exceeded in children who are unable to give us direct input as to how loud sounds are through the cochlear implant.

Parents and professionals working with the children will receive extensive counseling regarding how the equipment functions, maintenance and troubleshooting of the device, and progression of auditory skills of children who cochlear implants. This is accomplished during visits to the center and through in-service training offered locally via the fiberoptic teleconferences.

### *1.5.2 Programming Follow-up*

Following surgical implantation of the device and an adequate healing period, the implants will be activated (usually 4 to 6 weeks after surgery) and programmed. Thereafter, prior to the 4-month post-operative evaluation, two additional programming follow-up sessions will be scheduled at 2 weeks and 1 month as it is not unusual for threshold and comfort levels to change during the initial postactivation period. The follow-up sessions will allow the participant's T- and C-levels to be checked as well as any programming adjustments to be made based on the participant's initial experience with the device. Electrical impedance measures also will be obtained. Additional programming at additional postactivation intervals will be assessed and conducted as needed.

### *1.5.3 Listening Conditions*

The following describes the listening modes used by the child during each speech perception or speech/language measure:

- Nucleus L24 electrode array only (unilateral)
- Standard-length electrode array only (unilateral)
- Right and left ear devices used together (bilateral).

### *1.5.4 Speech Perception and Speech/Language Testing:*

Speech perception and speech/language development will be assessed longitudinally at 4, 8, 12, 18, 24, months, and annually thereafter through five years of age. The tests or questionnaires will be administered age appropriately.

#### 1.5.4.1 Speech Perception

- *The Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) or Meaningful Auditory Integration Scale (MAIS)* (Zimmerman-Phillips, Osberger, & Robbins, 1997) as described above in baseline/pre-operative testing will be collected. The MAIS is administered to children 25 months to 4 years 11 months.
- *The Glendonald Auditory Screening Procedure Word Test (GASP)* (Erber, 1982) contains 12 single-syllable and multisyllable words. The child will be tested in the bilateral listening condition. This test is always administered in a live-voice mode. The child is asked to repeat the word presented by the clinician. The child is encouraged to use sign if his or her verbal

approximations are not clear to the clinician. This test is the easiest open-set measure in this battery because it includes common vocabulary and the speaker is familiar. It can be administered to children as young as two years of age.

- *Iowa Children's Vowel Test* (Tyler, Fryauf-Bertschy, & Kelsay, 1991) requires the identification of a monosyllabic word from a closed set of four words (e.g., toe, toy, tie, two) varying only in vowel content (place and height). If the child performs at 80% or higher, multi-talker babble at a +7 dB-C S/N will be added. It will be administered in both the unilateral and bilateral listening conditions at 70 dB C.
- The *Early Speech Perception Four Choice Spondee and Monosyllable* (ESP, Moog & Geers, 1990) tests require the identification of a spondee or monosyllable from a set of four spondees (i.e., French fry, airplane, hotdog, popcorn) or monosyllables (i.e., ball, book, bird, boat), respectively presented in quiet. The CID test will be scored as total number of words correct. It will be administered in both the unilateral and bilateral listening conditions at 70 dB C.
- The *Multisyllabic Lexical Neighborhood Test* (MLNT, Kirk, Pisoni, & Osberger, 1993) and *Lexical Neighborhood Test* (LNT, Kirk, Pisoni, & Osberger, 1993) are two open-set word recognition tests. The experimenter gives a list of 24 words and the participants are expected to repeat the word after each presentation. The MLNT consists of two parallel lists. The LNT and MLNT are based on the lexical characteristics of word frequency and neighborhood density, and include words found in the vocabularies of children age three to five. The child will be tested in the bilateral listening condition at 70 dB C.
- *Phonetically Balanced-Kindergarten* (PB-K, Haskins, 1949) in quiet. The PB-K test has multiple 50 word lists. The test will be scored as total number of words correct as well as phonemically. It will be administered in both the unilateral and bilateral listening conditions at 70 dB C.

#### 1.5.4.1.1 Calibration

Speech perception will be calibrated using a calibration tone (or calibration sound file). A sound-level meter will be used to measure the dBC level of the calibration tone at a distance of 1 meter from the loudspeaker. The loudness will be adjusted through the audiometer or receiver to achieve the desired loudness level for the specific test.

### 1.5.4.2 Speech and Language Testing – all administered in the bilateral listening condition

- *Vocalizations/speech samples* as described above in baseline/pre-operative testing will be collected.
- *MacArthur Communicative* Developmental Inventories (CDI) and the Minnesota Child Development Inventory (MinnCDI, Ireton & Thwing, 1974) as described above in baseline/pre-operative testing will be collected.
- The *Preschool Language Scale-3 (PLS-3*), (Zimmerman, Steiner, & Pond, 1992) as described above in baseline/pre-operative testing will be collected.
- *Peabody Picture Vocabulary Development Scale (PPVT)*. The PPVT (Dunn & Dunn, 1997) is a standardized, norm-referenced measure of receptive vocabulary skills. The test is a multiple-choice measure consisting of sets of four black and white line drawings. The examiner names one of the pictures and the test recipient is expected to indicate which picture has been labeled, either verbally or through pointing.

- *Expressive Vocabulary Test*. This is an expressive vocabulary test that provides an index of expressive vocabulary skill.
- *Goldman-Fristoe Test of Articulation-2* (Goldman & Fristoe, 2000). The GFTA-2 is a standardized, norm-based articulation measure that samples spontaneous sound production. Children are asked to respond to picture plates and verbal cues from the examiner with single words that test consonant accuracy in initial, medial, and final positions. This measure has norms based on the performance of normal-hearing children from age 2 years to 21 years.

### *1.5.5 Psychophysical and Electrical Impedance Measurements:*

The following psychophysical and electrical impedance measurements will be attempted at 4, 8, 12, 18, 24 months, and annually thereafter through five years of age.

1. Electrical thresholds measured in current level.
2. Electrical maximum comfort levels measured in current level.
3. Impedance telemetry results using common ground (CG) and monopolar (MP1, MP2, MP1+2) stimulation modes.

## 1.6 Adverse Effects

Adverse effects are any undesirable clinical or medical occurrence associated with use of the device or participation in the study. Any adverse effects are to be reported to the FDA and our IRB via the “Adverse Effects Form”. The Primary Investigator will be required to verify that there are or there are no adverse effects to report.

Adverse effects will be reported if observed, even if acknowledged as risk factors in the consent. Adverse effects include:

1. Vertigo, dizziness, or balance problems that did not exist preoperatively or worsened postoperatively
2. Facial nerve problems
3. Meningitis
4. Perilymphatic fistulae
5. Tinnitus that did not exist preoperatively or worsened postoperatively
6. Implant Migration/Extrusion
7. Skin flap problems
8. Device-related/programming problems
9. Infection requiring explantation
10. Device failure requiring explantation

## 1.7 Unanticipated Adverse Events

Unanticipated adverse device effects refer to any event not identified above that represents a “serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device if that effect, problem or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.” [FDA 21 CFR 812.3(s)]

Investigators are to inform their respective Institutional Review Boards (IRBs) immediately if an unanticipated adverse device effect is suspected (no more than 10 working days after the investigator learns of the effect). If the case is determined to be an unanticipated adverse device effect, the investigator will fill out an "Unanticipated Adverse Device Effect Form." University of Iowa will report the results of an evaluation of the unanticipated adverse device effect to the FDA and all other reviewing IRBs and investigators within 10 working days after first receiving notice of the event.

## 1.8 Data Analysis

In order to assess the feasibility of using the Nucleus L24 electrode and the standard-length arrays on contralateral ears, data will be analyzed individually and with group statistics. Because the children implanted in this study will be 12-24 months of age at time of implantation, outcomes as to the success of this study may become clearer as the child ages and their speech and language skills develop. Thus, our primary measure of assessment will change as the child becomes older.

We will measure success of this study by assessing speech perception and speech/language development as described above in the test descriptions (see 1.5.4). We will attempt to compare these results with age-matched children implanted with standard-length bilateral devices on both ears on the same speech perception and speech/language measures. In addition, if possible, we will attempt to compare the same speech perception and speech/language measures on age-matched children implanted with a standard-length device on one ear and a Nucleus S12 implant on the contralateral ear. The independent variable will be whether the child receives Nucleus L24 and standard-length electrode arrays on contralateral ears, bilateral standard-length devices, or a standard-length device on one ear and a Nucleus S12 implant on the contralateral ear. The dependent variables will be a set of speech perception and speech/language measures suitable for tracking growth of these traits.

Because this is a feasibility study, we will only be implanting up to 15 infants with Nucleus L24 and standard-length electrode arrays on contralateral ears. We recognize that this small number of subjects may not afford us enough statistical power to adequately answer all questions associated with using these different length electrode arrays in pediatric subjects who have bilateral profound hearing loss. However, it may lend us foundational knowledge to assess whether the device configurations can provide useful bilateral hearing while possibly preserving the scala media, organ of Corti and supporting cells of the ear for future advances in molecular and/or genetic treatments of the inner ear.

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