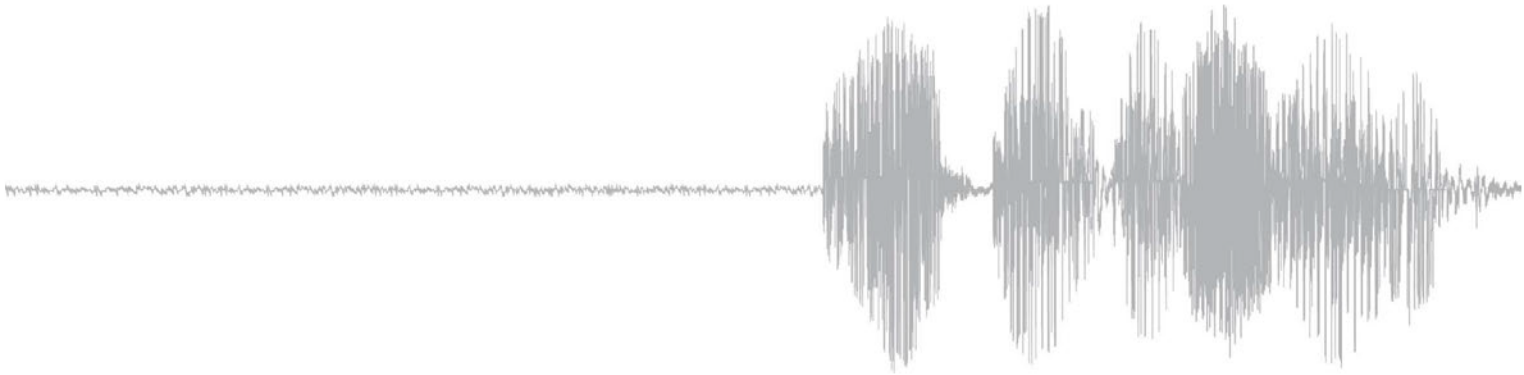

FLI normative CIP single visit

D1197624

Version: 2
State: Approved (T+B)
Approver: Mary Beth Brinson (Mbbrinson)
Date : 07 Jan 2019

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Number of pages (include Coversheet): 21

Clinical Investigation Plan

Normative Data for the Functional Listening Index – Paediatric (FLI-P)

FLI Study

Investigation Number: CLTD5703

Version Number: 2.0

Date: 12-OCT-2018

Author: Michelle Knight

Sponsor	Cochlear Limited 1 University Avenue Macquarie University NSW 2109
Coordinating Investigator	Aleisha Davis Project Leader, The HEARing CRC General Manager, Clinical Programs The Shepherd Centre 146 Burren Street Newtown NSW 2012
Contract Research Organisation	The HEARing CRC 550 Swanston Street Department of Audiology and Speech Pathology The University of Melbourne Carlton Victoria 3053

1 SPONSOR AND COORDINATING INVESTIGATOR SIGNED AGREEMENT

Investigation Title	Normative Data for the Functional Listening Index – Paediatric (FLI-P).
Investigation Number	CLTD5703
Short title	FLI Study

Signature on behalf of Sponsor

I agree with the content in this clinical investigation plan, including all appendices.

Name	**Title**
[redacted]	[redacted]
Signature	**Date** (dd-mmm-yyyy)

Signature of Coordinating Investigator

I agree to the content of this clinical investigation plan, including all appendices.

Name	**Title**
[redacted]	[redacted]
Signature	**Date** (dd-mmm-yyyy)

Signature of Responsible Contract Research Organisation

I agree to the content of this clinical investigation plan, including all appendices, and undertake that the Contract Research Organisation will conduct the research study in accordance with this plan.

Name	**Title**
[redacted]	[redacted]
Signature	**Date** (dd-mmm-yyyy)

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2 CLINICAL INVESTIGATION SYNOPSIS

Investigation title	Normative Data for the Functional Listening Index – Paediatric (FLI-P).
Investigation number	CLTD5703
Short title	FLI Study[1]
Name of investigational device	Functional Listening Index – Paediatric (FLI-P)
Investigation start	July 2017
Total expected duration of the clinical investigation	Two years
Enrolment period	Two years
Expected duration per subject	Single visit or electronic data submission by parents/caregivers.
Investigational design	Multiple center, cross sectional observational research design.
Number of subjects	Up to 1500 Normally-hearing children
Inclusion criteria	1. Children aged between 0 and 6 years of age. 2. PASS on the Newborn Hearing Screen Status conducted during the New South Wales Statewide Infant Screening - Hearing (SWISH) Program. 3. No current parental or professional concern regarding hearing status.
Exclusion criteria	1. Pre-existing diagnosis of additional needs. 2. Unrealistic expectations on the part of the subject, regarding the possible benefits, risks, and limitations of the study. 3. Unwillingness or inability of the subject to comply with all investigational requirements.
Primary objective	The assessment of listening skill acquisition in normally-hearing children aged between 0 and 6 years with the Functional Listening Index – Paediatric (FLI-P)
Investigation schedule	**Procedure** / **Data collection** Consent / X Eligibility / X Demographics / X FLI-P / X
Primary endpoint	Normative database for acquisition of listening skills in children aged between 0 and 6 years with the Functional Listening Index – Paediatric (FLI-P).

[1] As registered on ClinicalTrials.gov

3 IDENTIFICATION AND DESCRIPTION OF THE INVESTIGATIONAL DEVICE

The Functional Listening Index – Paediatric (FLI-P), is an assessment tool developed by The Shepherd Centre and The HEARing CRC (1-3). The FLI-P has been developed to address a substantial gap in the current tools available to measure the development of auditory skills in children. The FLI-P provides a measure of listening skills acquisition in children from birth to six years of age (0 – 72 months).

As the development of listening skills are a necessary precursor to the acquisition of spoken language skills, it is hypothesized that tracking a child's progress in listening will be predictive of later spoken language outcomes. The FLI-P measures the acquisition of listening skills from the earliest skills from birth through to advanced listening skills required in the early school years. The FLI-P is intended to provide evidence to clinicians to enable them to act before the impact of poor listening on speech and language becomes apparent and delays exist. It has provided objective information and evidence for families and clinicians, directed changes in clinical management and intervention decisions and improved speech and language outcomes (1-3).

The FLI-P is potentially a more efficient and effective measure of listening skills as compared to current auditory skill assessments, such as objective speech perception assessments and the subjective listening skill checklists as its sensitivity is not as impacted by ceiling effects and the same measures are used over time to provide a trajectory of the development of listening skills. The FLI-P also incorporates a cognitive component as it assesses how the acquisition of listening skills impacts children's behaviour and learning, rather than simply an assessment of detection and imitation. The FLI-P will be used to assess development of listening skills in normally hearing children as a function of age in the current clinical investigation (FLI Study). The FLI-P will be administered by an investigator who has received appropriate training in its use or completed by parents/caregivers themselves. The FLI-P assessment will be conducted using an application running on a PC, tablet or online device. There are no specific medical or surgical procedures involved in this clinical investigation and the FLI-P is a non-interventional application.

4 JUSTIFICATION FOR THE DESIGN OF THE CLINICAL INVESTIGATION

Hearing loss is the most common disability now diagnosed at birth through the implementation of universal newborn screening programs (4). The impacts of hearing loss on language development and communication outcomes in young children have been well-documented, and include such effects as delayed speech and language development (5); lesser long term academic and educational achievement (6); issues in development of social and emotional skills (7); lesser employment opportunities (8); as well as impacts on mental health and quality of life (9) when compared with normal hearing peers.

The advent of early intervention programs including early fitting of hearing prostheses has been shown to be critical in improving outcomes for these children (10). However, access to accurate, evidence based information on the development of language and communication

skills for children with hearing loss is critical for both parents and professionals to guide decisions on interventions and technology choices.

A cross-sectional observational research design is appropriate for this clinical investigation since the FLI-P is not an intervention and the primary objective of the study is to collect data on a variety of subject populations at a single point in time. The clinical investigation will collect data for the FLI-P in normally-hearing children aged between 0 and 6 years (0 and 72 months) during a single visit, providing normative data on the development of listening skills as a function of age. This normative FLI-P data will be used by Cochlear Limited in the formation of a database, for which the trajectory of development of listening skills for children receiving cochlear implants can be compared with their normally-hearing peers.

5 RISKS AND BENEFITS OF THE INVESTIGATIONAL DEVICE AND CLINICAL INVESTIGATION

The anticipated clinical benefits of participation in the clinical investigation is the collection of objective information on the development of listening skills for normally-hearing children. The data collected as part of the clinical investigation can be informative for the child's parent or caregiver, health professional or teacher to inform changes in parent/caregiver interaction and educational management with the goal of leading to improved speech and language outcomes.

There are no specific risks associated with participation in the clinical investigation or in undertaking assessment with the FLI-P. The FLI-P has been in regular clinical use at The Shepherd Centre Early Intervention program for children with hearing loss and their families since August 2014.In addition, there are no anticipated adverse device effects related to the use of the FLI-P in this clinical investigation.

The assessments will be undertaken either by an investigator trained in the administration of the FLI-P whilst the child is in the care of their parent or caregiver, or by the parent/caregiver themselves after due instruction. Participation in the clinical investigation is voluntary and consent and participation can be withdrawn at any time.

If there are any concerns or questions arising from participation in the clinical investigation, the Principal Investigator's details will be provided to the parent/caregiver so that they may contact to follow up regarding their score and next steps. The Principal Investigator has been working clinically in the field with children and families for over 10 years, and is well-placed to provide this clinical consultation and direction. Therefore risk-to-benefit rationale for participation in this clinical investigation is considered to be positive.

6 OBJECTIVES AND HYPOTHESES

6.1 Objective

The primary objective of the clinical investigation is the assessment of listening skill acquisition in normally hearing children aged between 0 and 6 years with the Functional Listening Index – Paediatric (FLI-P).

6.2 Hypotheses

As this clinical investigation aims to collect data on normally hearing (NH) subject populations at numerous points in time, there are no hypotheses to be accepted or rejected by statistical data.

7 DESIGN OF THE CLINICAL INVESTIGATION

7.1 General

The study will be conducted using a multiple-centre, cross-sectional observational design. A cross-sectional observational research design is appropriate since the Functional Listening Index - Paediatric (FLI-P) is not an intervention and the primary objective of the study is to collect normative data on a normally hearing paediatric populations.

There are no measures to be taken to minimize or avoid bias in the clinical investigation as all participants will undergo assessment with the FLI-P.

7.2 Endpoint

The primary endpoint for the clinical investigation is a normative database for acquisition of listening skills in children aged between 0 and 6 years as assessed with the Functional Listening Index – Paediatric (FLI-P).

7.3 Investigation schedule

Table 1 displays the measures to be applied during the clinical investigation.

Procedure	Data collection
Consent	X
Eligibility	X
Demographics	X
FLI-P	X

Parents/caregivers who have previously attended the MARCS Institute BabyLab, Macquarie University Child Language Lab, or The Shepherd Centre with their children will be invited to participate in the clinical investigation via email. Parents/caregivers currently attending MARCS Institute BabyLab, Macquarie University Child Language Lab, or The Shepherd Centre with their children will be invited to participate in the clinical investigation in person.

7.4 Investigational device and comparator

The Functional Listening Index – Pediatric (FLI-P) is a digital internet-based application which can be accessed by health professionals or parents/caregivers using their computer, tablet or online device. Data may be collected using the FLI-P during a single visit to the MARCS Institute BabyLab, Child Language Lab, Child Language Lab, or The Shepherd

Centre, or via an electronic link sent to parents/caregivers via email. There is no comparator device to be assessed as part of the clinical investigation.

7.5 Subjects

The eligibility criteria for the clinical investigation are described below.

7.5.1 Inclusion criteria

1. Children aged between 0 and 6 years of age.
2. PASS on the Newborn Hearing Screen Status conducted during the New South Wales Statewide Infant Screening - Hearing (SWISH) Program.
3. No current parental or professional concern regarding hearing status.

7.5.2 Exclusion criteria

1. Pre-existing diagnosis of additional needs.
2. Unrealistic expectations on the part of the subject, regarding the possible benefits, risks, and limitations of the study.
3. Unwillingness or inability of the subject to comply with all investigational requirements.

7.5.3 Subject withdrawal

Subjects are free to withdraw from the clinical investigation at any time and without having to provide a reason for withdrawal.

7.5.4 Subject enrolment

Subjects will be recruited for the clinical investigation from children currently attending or children who have previously attended MARCS Institute BabyLab, Macquarie University Child Language Lab, or The Shepherd Centre.

Parents/caregivers of children currently attending or who have previously attended MARCS Institute BabyLab, Macquarie University Child Language Lab, or The Shepherd Centre will be invited to participate in the clinical investigation via email or when they attend in person at MARCS BabyLab, Macquarie University Child Language Lab, or The Shepherd Centre. They will be provided with information about the clinical investigation, and indicate if they are willing to participate. Subjects will be recruited for the clinical investigation until the minimum required number of subjects (36) in each age block is met. The anticipated enrolment rate of 50% considered the following factors:

- Proportion of parents who indicated an interest in participating
- Proportion of children who meet eligibility criteria for the investigation
- Proportion of parents who successfully entered data into the Qualtrics website.

As enrollment during the first few months of the clinical investigation was below the rate needed to meet the minimum subject enrollment (n=432), two additional sites were added (Macquarie University Child Language Lab, and The Shepherd Centre), up to 1500 families were identified from MARCS Institute BabyLab database, Macquarie University Child Language Lab database, or The Shepherd Centre database, and sent an invitation email to provide up to 600 responses (anticipated 40% response rate). To accommodate a low

completion rate, eligibility failures and distribution of numbers by age stratification, a larger group was invited to participate in order to meet the minimum subject enrollment (n=432) for statistical significance. As there is no control mechanism to close enrolment once recruitment for the minimum number in each age block is complete, enrolment will continue until the minimum required number is met for all age blocks. All data collected will form part of the statistical analysis.

The total expected duration of the clinical investigation is two years. The expected duration of each subject's participation is a single visit or no visit (if completed via email link). The minimum number of subjects required for the clinical investigation is 432 children across twelve age blocks. The subject recruitment age blocks for the clinical investigation are described in Table 1 below. The age of each subject will be reported and the number of subjects within each age block will be reported.

Table 1. Minimum requirement subject recruitment age blocks (mths).

Age (mths)	No. of subjects
0-6	36
7-12	36
13-18	36
19-24	36
25-30	36
31-36	36
37-42	36
43-48	36
49-54	36
55-60	36
61-66	36
67-72	36
Total	**432**

The estimated time needed to select this number (i.e. enrolment period) is two years.

7.6 Procedures

7.6.1 Invitation to participate

An invitation to participate will be sent out via email to parents/caregivers of children who have previously attended MARCS BabyLab at Western Sydney, Macquarie University Child Language Lab, or The Shepherd Centre. In addition, parents/caregivers who are currently attending MARCS BabyLab at Western Sydney University, Macquarie University Child

Language Lab, or The Shepherd Centre will be invited to participate in the FLI Study in person.

7.6.2 Consent and eligibility assessment

Once parents/caregivers indicate they are interested in participating they will be provided with a link to the FLI Study Qualtrics platform (via email or an online device at MARCS BabyLab, Macquarie University Child Language Lab, or The Shepherd Centre).

Clinical investigation related activities such as consent, eligibility and link to the FLI-P assessment will be performed using the FLI Study Qualtrics platform.

Participant informed consent will be provided digitally prior to any clinical investigation related activities taking place. Eligibility to participate in the clinical investigation will be determined by investigator or parent/caregiver answers to questions on the FLI Study Qualtrics platform.

7.6.3 Assessment

Investigator or parents/carers are only provided access to the FLI-P link when digital consent is obtained and eligibility confirmed in the FLI Study Qualtrics platform.

Subject demographics and listening skills status will be assessed and recorded by the investigator or parent/caregiver with the FLI-P application by indicating if each skill has been observed or demonstrated. The FLI-P has examples and elicitation methods for each item if the investigator or parent/caregiver are unsure.

No information about the child's performance on the FLI-P will be provided at the time of assessment. Parents or caregivers can however contact the Principal Investigator for feedback on their child's performance on the FLI-P.

Name of Principal Investigator	[redacted]
Phone number (business hours)	[redacted]
E-mail	[redacted]

7.6.4 Activities performed by Sponsor representatives

Activities to be performed by Sponsor representatives excluding monitoring include:

1. Application of clinical quality assurance and quality control principles to the processes of the clinical investigation according to the Cochlear Limited Quality Manual (11).
2. Clinical investigation planning and conduct
    a. Site selection for the clinical investigation.
    b. Preparation of documents and materials for the clinical investigation.
    c. Conduct of the clinical investigation i.e. accountability of investigational devices, clinical trial insurance coverage, research agreements between Contract Research Organisation (CRO) and Sponsor.
3. Clinical investigation close-out and final report.

7.6.5 Known or foreseeable factors

There are no known or foreseeable factors that may compromise the outcome of the clinical investigation or the interpretation of results obtained with the FLI-P. The increased enrolment of up to 600 responses does not increase the Type 1 error rate as the decision was made without interim analysis of the data. An increased sample size provides less than 10% probability of an error ≥ 2 at each whole-number age from 1 month to 72 months.

7.6.6 Subjects medical care post-investigation

As the FLI-P is not an intervention, and the clinical investigation involves either a single visit to MARCS Institute BabyLab or data collection via email. No medical care is envisioned to be required for subjects after the clinical investigation has been completed.

7.7 Monitoring Plan

The clinical investigation shall be monitored according to the Clinical Investigation Monitoring Work Instruction (12) by monitors who are GCP qualified. The investigational site shall be monitored for their compliance with applicable regulations, the Clinical Investigational Protocol (CIP), digital Patient Information Consent (PIC), inclusion and exclusion criteria of the participants and Sponsor-specific requirements.

A risk-based monitoring plan will be undertaken for the clinical investigation, whereby:

a) 100% of the digital PIC will be monitored.

b) The first monitoring visit will be conducted after the five subjects have completed the clinical investigation. All (i.e. 100%) of data shall be verified for completion during the first monitoring visit. If more than 30% of data are found to be incomplete, additional interim monitoring visits may be scheduled.

c) The second monitoring visit will be conducted after the completion of data collection. 30% of the data shall be verified for completion during the second monitoring visit. If data errors are found in 50% of the data verified during monitoring, then data verification for completion will be done on 100% of the data.

8 STATISTICAL CONSIDERATIONS

The criterion for the sample size was that the 50th, 84th and 16th percentiles of the FLI-P score are to be estimated as functions of age with at least 90% probability of an error no greater than two at each whole-number age from 1 month to 72 months. The 50th, 84th and 16th percentiles are considered because they correspond to the mean, mean plus one standard deviation, and mean minus one standard deviation, respectively, in a normal distribution. Using a Monte Carlo simulation approach, and assuming an equal number of subjects in each 6-month age band, the required sample size was estimated as 36 subjects in each 6-month age band. This equates to a minimum enrolment of 432 subjects for the clinical investigation.

9 DATA MANAGEMENT

9.1 Electronic source data collection

Participant informed consent and eligibility criteria will be directly entered by the parent or caregiver into the FLI Study Qualtrics platform on a PC, tablet or online device. Instructions are provided in the FLI Study Qualtrics platform for parents/caregivers.

Subject demographic and FLI-P source data will be directly entered into the FLI-P application by the investigator or parent/caregiver on a PC, tablet or online device. Clinical investigators will be trained to use this application, and instructions and examples are provided in FLI-P for parents/caregivers.

9.2 Clinical investigation data management

Qualtrics is a secure online platform that has been previously utilized by MARCS BabyLab for digital consent in clinical investigations. The FLI-P application is a secure online platform that has been previously utilized by The Shepherd Centre for source data collection during clinical investigations.

The investigation-specific data in Qualtrics platform and FLI-P application can only be accessed by those individuals that have been allocated an account, which are personnel of the investigational site, Clinical Project Manager, Investigation Monitors and Data Management based on the individual's role. An audit trail is kept by the Qualtrics platform and FLI-P application.

10 AMENDMENTS TO THE CIP

No changes in the CIP or investigation procedures shall be effected without mutual agreement of the Principal Investigator, the responsible Contract Research Organisation (CRO) and the Sponsor. Changes related to the scientific intent of the study shall be documented in the CIP and requires signatures from the Sponsor and the coordinating investigator. Such changes will require notification to the Western Sydney University Human Research Ethics Committee (WSU HREC) by the Principal Investigator.

11 DEVIATIONS FROM THE CIP

The investigator is not allowed to deviate from the CIP except under emergency circumstances to protect the rights, safety and well-being of the subjects. Such deviation shall be documented and reported to the Sponsor and the Western Sydney University Human Research Ethics Committee (WSU HREC) as soon as possible.

12 DEVICE ACCOUNTABILITY

No devices shall be provided as part of this clinical investigation. The FLI-P is a web-based application which can be accessed on a PC, tablet or online device.

13 STATEMENTS OF COMPLIANCE

13.1 Declaration of Helsinki and compliance with Standards

The clinical investigation shall be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki (2013) and The National Statement on Ethical Conduct in Human Research (2007), as appropriate.

13.2 Ethics Committee and Competent Authority Approval

The clinical investigation shall not commence prior to the written favourable opinion or approval from the Western Sydney University Human Research Ethics Committee (WSU HREC) is obtained.

The Principal Investigator shall submit the final approved version of the CIP, the approved PIC and all subsequently approved documents to the WSU HREC. A copy of the WSU HREC recommendation/approval shall be provided to the Sponsor.

The Principal Investigator shall forward any amendment to be made to the approved PIC, or any other written information to be provided to the subject for review and approval by the Sponsor prior to submission to the WSU HREC.

The Sponsor and Principal Investigator shall continue the communication with the WSU HREC as required by national regulations or the Clinical Investigation Plan (CIP).

Any additional requirements imposed by the WSU HREC shall be followed.

The investigator shall submit the appropriate documentation if any extension or renewal of the WSU HREC approval is required. In particular substantial amendments to the CIP, the PIC, or other written information provided to subjects shall be approved in writing by the WSU HREC.

The investigator will report to the WSU HREC any new information that may affect the safety of the subjects or the conduct of the clinical investigation. The investigator shall send written status summaries of the investigation as per WSU HREC requirements.

Upon completion of the clinical investigation, the investigator shall provide the WSU HREC with a brief report of the outcome of the clinical investigation as per requirements.

The clinical investigation is covered by a clinical trial insurance meeting the Australian requirements.

14 INFORMED CONSENT PROCESS

14.1 Obtaining informed consent

Informed consent shall be obtained digitally using an approved Patient Informed Consent (PIC) on the FLI Study Qualtrics® platform. The rationale for, details and objectives of the investigation, and the extent of the subject's involvement shall be provided. Ample time shall be provided for the subject's parent or caregiver to inquire about details of the clinical investigation and to decide whether to participate. Parents/caregivers indicate their consent

to participate by entering their name and date and clicking a checkbox on the Qualtrics platform.

The Qualtrics platform has been previously used by the MARCS Institute BabyLab as a means of obtaining digital informed consent for clinical investigations.

For participants attending MARCS Institute BabyLab, Macquarie University Child Language Lab, or The Shepherd Centre, the investigator shall provide the tablet, PC or other online device to the parent or caregiver to obtain digital informed consent prior to any clinical investigation related examination or activity. For participants invited to participate in the clinical investigation via email, an invitation to the FLI Study Qualtrics platform will be provided to parents/caregivers who have indicated a willingness to participate.

All questions about the clinical investigation shall be answered to the satisfaction of the subject or the subject's legally acceptable representative. Subjects, their parent or caregiver shall not be coerced or unduly influenced to participate in a clinical investigation.

The digital consent records will be maintained at the investigational site for a minimum of 15 years after completion of the clinical investigation.

14.2 Data Privacy

The FLI-P application generates a unique identification code. This de-identified data will only be available to the Sponsor and their representatives, the investigators, and if requested to the Western Sydney University Human Research Ethics Committee (WSU HREC).

15 Reporting Process for Adverse Events, Adverse Device Effects and Device Deficiencies

15.1 Definitions

All definitions are according to the EN ISO 14155:2011 standard and described in Section 21.1.

15.2 The reporting process for adverse events, adverse device effects and device deficiencies

There are no anticipated adverse events or anticipated adverse device effects associated with the use of the FLI-P within the clinical investigation.

In the unlikely situation an adverse event occurs during the clinical investigation, the Principal Investigator shall ensure that this is properly recorded and reported to the Sponsor.

Name of contact person of the Sponsor	[redacted]
Phone number (business hours)	[redacted]
Phone number (after hours)	[redacted]
E-mail	[redacted]

The Principal Investigator will be responsible for reporting any AEs, SAEs, SADEs or USADEs to the Western Sydney University Human Research Ethics Committee (WSU HREC), and any other applicable Ethics Committee as required by the Contract Research Organisation (CRO), using the applicable report form as per national requirement.

Subjects shall be carefully monitored during the clinical investigation for potential adverse events. The investigator shall attempt to assess the relationship between the investigational device and the adverse event.

15.3 Data Monitoring Committee

Not applicable for the current clinical investigation as the risk-to-benefit rationale for participation in this clinical investigation is considered to be positive.

Medical occurrences that are related to pre-existing conditions (e.g. diabetes, allergies and asthma) are considered as unexpected adverse events in the frame of the clinical investigation.

15.4 Device deficiency reporting requirements

The investigator shall report any device deficiency without unjustifiable delay to the Sponsor.

Name of contact person of the Sponsor	[redacted]
Phone number (business hours)	[redacted]
Phone number (after hours)	[redacted]
E-mail	[redacted]

16 INCIDENT REPORTING

Not applicable for the current clinical investigation as no investigational products are CE marked.

17 VULNERABLE POPULATION

Candidates for the clinical investigation are aged between 0 and 6 years and are considered to be a vulnerable population.

Participant Informed Consent for the clinical investigation will be obtained from the parent or caregiver digitally using the FLI Study Qualtrics platform.

18 SUSPENSION OR PREMATURE TERMINATION

The Sponsor will withdraw from sponsorship of the clinical investigation if:

1. major non-adherence to the CIP is occurring
2. it is anticipated that the subject recruitment will not be adequate to meet the objectives of the clinical investigation

Should the Sponsor withdraw from sponsorship of the clinical investigation, the Sponsor will continue sponsorship for the subjects already recruited into the investigation.

An ongoing clinical investigation can be discontinued in case of:

1. investigator's decision
2. subject's decision

19 PUBLICATION POLICY

It is planned to generate a joint publication and presentations by the clinical investigators and the Sponsor. The responsibility for writing the initial publication will rest with the Principal Investigator (to be discussed and agreed with the CRO and Sponsor prior to investigation start). The initial joint publication and any associated or planned conference presentations must be reviewed by the Sponsor at least 30 days in advance to any release or publication. If the publication or presentations contain information that the CRO and/or Sponsor at their individual discretion, deems worth protecting in the form of a patent or trademark etc., the CRO or Sponsor has the right to delay the publication or presentation for 90 days.

Following acceptance of the joint publication, the investigators will be able to publish as they wish, provided always that appropriate acknowledgement of the inventors of the FLI-P are included in any publication. The publishing investigator will provide the Principal Investigator and Sponsor with a manuscript copy of the abstract and paper at least 30 days in advance of publication or presentation. If the publication contains information that the Sponsor at his discretion finds worth protecting in the form of a patent or trademark etc., the Sponsor has the right to withhold the publication or presentation for 90 days

20 CHANGE HISTORY

Version	Change	Author	Date
1.0	Introduction of document	[redacted]	03/07/2017
2.0	Upissued document to extend recruitment up to n=1500 to meet minimum enrolment. Addition of Macquarie University Child Language Lab, and The Shepherd Centre as investigational sites.	[redacted]	03/10/2018

21 DEFINITIONS

21.1 Definitions from ISO 14155:2011

Term
Adverse event (AE)

Term
Adverse device effect (ADE)
Device deficiency (DD)
Incident
Serious adverse event (SAE)
Serious adverse device effect (SADE)
Unanticipated serious adverse device effect (USADE)

21.2 Other definitions

Term	Description
CIP	Clinical Investigation Plan
CRF	Case Report Form
CRO	Contract Research Organisation
HREC	Human Research Ethics Committee
FLI-P	Functional Listening Index - Paediatric
NH	Normally Hearing
PC	Personal Computer
PIC	Patient Informed Consent form
WSU	Western Sydney University

22 REFERENCE LIST

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