The diagnostic accuracy of hearing tests and cost-effectiveness of school entry hearing screening programmes

SES Study 1 Case child: ID number								
Date of Screen:	Date of Screen:							
Location of test: Clin [circle as require		NHBRU / Oth	er, please state					
Background noise level:	dB Note	s:						
Background informat	ion							
Location of hospital:		Dat	te of Birth:		(DD/MM/YYYY)			
Gender [circle as require	ed]: Male / F	emale Pos	t code:					
Ethnicity [tick as required]:  Known medical conditions [List below]:    White								
Pure Tone then Hearche	eck 🗆	Hearchecl	k then Pure Tone					
Order of ears for the 2 t	ests? [record o	overleaf too]						
Left, right 🛛		Right, left						
Pure Tone Sweep results								
	Frequenc	y detected? [tick	if heard, cross if no	ot heard]	Initials of screener:			
First test (20db)	1kHz	2kHz	4kHz	500Hz				
Left Ear	1kHz	2kHz	4kHz	500Hz	Time taken			
Right Ear				500112	(mins):			
Analysis: (tick p	Right Ear	, [ ] ]						
3/3 or 2/3 respo	onses at every fre	Pass 🗆	Pass 🗆					
1/3 or 0/3 respo								

SES study 1 - CRF case children - v 1.3 26.09.13

NRES ref: 12/WM/0195, Sponsor ref: 12064, Ethics ref: 106333, NIHR HTA10/63/03

The dia	agnosti												
ID Nur	mber:		DO	B:				ſ	ostcod	le:			
Hoor	bock S	weep Results											
		o test first?	Left			Dia	ht 🗆						
vviiici	l ear to		Leit			rigi							Initials of
				1KHz			3KHz						screener
			55dB	35dB	20dB	75dB	55dB	35dE					
		Left Ear							Tota	al heard	/	6	
		Right Ear							Tota	al heard	/	6	Time tak
	Ana	ysis: (tick pass o	r fail)				Le	ft Ear			Right E	ar	(mins):
	Hear	rd all 6 tones in b	oth ears	?			Ра	ss 🗆		I	Pass 🗆	]	
	Hear	rd 0-5 tones in ei	ther ear	?			Fa	il 🗆			Fail 🗆	]	
		vas actually done d the second res	earcher		rcheck f <b>the cl</b>			re Tone iiled the		creen?			
<u>Blindi</u>	n <u>g:</u> Di If ye	d the second res Yes □ s, please explain	earcher No 🗆	know if	f the cl	nild pass	ed or fa			creen?			
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Blindin Hearin	n <u>g:</u> Di If ye	d the second res Yes s, please explain tory from Pure Date of PTA(dd, PTA attac RESUL	earcher No Tone A /mm/yyy hed? TS AC (dBA)	know if udiogr /y):	f the cl	nild passo	ed or fa	N ncy	e first s		○ X Δ	Right Left Unm Right	AC AC asked BC t BC
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Blindin Heari of cher eting	n <u>g:</u> Di If ye	d the second res Yes s, please explain tory from Pure Date of PTA(dd, PTA attac RESUL SF/Binaural / Right AC (	earcher No Tone A /mm/yyy ched? TS AC (dBA) (dBHL) dBHL)	know if udiogr /y):	f the cl	nild passo	ed or fa	N ncy	e first s		Ο Χ Δ [ ] 0-20	Right Left / Unm Right Left F	AC AC asked BC t BC 3C . Normal
Blindin Heari of cher eting	n <u>g:</u> Di If ye	d the second res Yes s, please explain tory from Pure Date of PTA(dd, PTA attac RESUL SF/Binaural / Right AC ( Left AC (c	TS AC (dBA) (dBHL) d BC (dB	know if udiogr /y): 25	f the cl	nild passo	ed or fa	N ncy	e first s		Ο Χ Δ [ ] 0-20 21-4	Right Left / Unm Right Left F D dBHL	AC AC asked BC t BC 3C . Normal Id Loss
Blindin Heari of cher eting	n <u>g:</u> Di If ye	d the second res Yes s, please explain tory from Pure Date of PTA(dd, PTA attac RESUL SF/Binaural / Right AC ( Left AC (c Right Unmasked	Tone A /mm/yyy ched? TS AC (dBA) (dBHL) dBHL) dBC (dBH BC (dBH BC (dBH	know if udiogr /y): 25 25 25 4 4 1 1 1	f the cl	nild passo	ed or fa	N ncy	e first s		○ X Δ [ ] 0-20 21-4 41-7	Right Left / Unm Right Left E O dBHL 40 Mi 70 M	AC asked BC t BC 3C . Normal

Circle as appropriate Tymps Right Tymps Left (Required when there is no BC) A B C A B C

SES study 1 - CRF case children - v 1.3 26.09.13

NRES ref: 12/WM/0195, Sponsor ref: 12064, Ethics ref: 106333, NIHR HTA10/63/03

The diagnostic accuracy of hearing tests and cost-effectiveness of school entry hearing screening programmes

ID Number:

DOB: DOB: Postcode: DOB

**REPEAT AUDIOGRAM** 

Date of Repeat Audiogram(dd/mm/yyyy):								
PTA attached?			Υ /	Ν				
RESULTS	Frequency							
RESOLIS	250Hz	500Hz	1kHz	2kHz	4kHz	8kHz		
SF/Binaural AC (dBA)								
Right AC (dBHL)								
Left AC (dBHL)								
Right Unmasked BC (dBHL)								
Left Unmasked BC (dBHL)								
Right Masked BC (dBHL)								
Left Masked BC (dBHL)								
Circle as appropriate	Ту	mps Righ	nt	Ту	ymps Le	eft		
(Required when there is no BC)	А	В	С	А	В	С		

The diagnostic accuracy of hearing tests and	d cost-effectiveness of school entry hea	ring screening programmes
ID Number: DOB:		Postcode:
Would parent(s) like a summary of the	project to be sent to them?	Y / N
[Note down preferred contact details]		
Is another PTA required (out of dat	e/incomplete?)	
Details of the request (BY PHONE) f	or repeat audiogram:	
Name of audiologist:		
Name of researcher:		[signature]
		[- ]- ]- ]- ]- ]- ]- ]- ]- ]- ]- ]- ]- ]-
Date of request:		Μ/ΥΥΥΥ)

The diagnostic accuracy of hearing tests and cost-effectiveness of school entry hearing screening programmes

SES Research testing	Study 1	Contro	ol chile	d – ID r	number	•		
Date of screen:			D/MM/	YYYY)				
Location of test [circle as re					Other.	please state		
Background noise level:								-
								-
Background information								
Name of School:				Date o	of Birth:			D/MM/YYYY)
Gender [circle as required]:	Male	/ Fema	le	Post	code:			
Ethnicity [tick as required]:				Know	n medica	al conditions [	List below]:	
White								
Mixed / Multiple e	hnic groups	;						
Asian / Asian	British							
Black / African / Caribbe		ritish						
Other ethnic	group							
Procedural information [	pre-rand	omised	1					
Order of sweep tests?								
Pure Tone then Hearcheck			Неа	rcheck t	hen Pure	e Tone 🛛		
r dre rone then nedreneek			ricu	encont				
Order of ears for the 3 test	? [Record	l overlea	af too]					
Left, right, left 🛛			Righ	t, left, ri	ght 🗆			
-			-		-			
Pure Tone Sweep results								1
			ncy det		tick if he	ard, cross if no		Time taken
First test (20db)	1	LkHz		2kHz		4kHz	500Hz	(mins):
Left Ear				264-		41415	F00U-	
Right Ear		LkHz		2kHz		4kHz	500Hz	
Analysis: (tick pass	or fail)			1 1	Left	Ear	Right Ear	
		froquo	201				Pass	Initials
3/3 or 2/3 response					Pass		PdSS 🗆	of
1/3 or 0/3 response	s for at le	ast one	frequer	су	Fail		Fail 🗆	screener
HearCheck Sweep Result	5							
	<u>,</u> 1KHz			3KHz				Time taken
55d	1	20dB	75dB	55dB	35dB			(mins):
Left Ear						Total heard	/6	
Right Ear						Total heard	/6	
Analysis: (tick pass	or fail)	•		•	Left	Ear	Right Ear	
Heard all 6 tones in	both ears	?			Pass		Pass 🗆	
Heard 0-5 tones in e	either ear	?			Fail		Fail 🗆	
Which test was act			Цор	rcheck [		Pure Tone		
which lest was del			пеа		<b>_</b>	rule lulle		

The	diagnostic a	accuracy of hearing t	ests and	cost-eff	ectivene	ess of sc	hool entry	hearing s	creen	ing programmes ID
Nu	mber:		D	ов: 🗌		_/_			Post	tcode:
[2 <sup>nd</sup> res					ly after	<u>both sc</u> Right		tests hav	<u>e bee</u>	en completed by the 1
Initials of										
tester:		RESULTS			Free	quency				KEY to read PTA:
			1kHz	2kHz	4kHz	8kHz	500Hz	250Hz		0-20 dBHL Normal
	-	Right AC (dBHL)								21-40 Mild Loss
Time taken		Left AC (dBHL)								41-70 Moderate Loss
(mins):										71-95 Severe Loss
										> 95 Profound Loss
PTA	results at	tached (printed ou	t)? Y	/ N						
PTA	A Result:	Normal / Re	fer [	circle as	s requir	ed]				

[Refer to Audiology if any frequencies <a>30dBHL are not heard]</a>

Blinding: Did the second researcher know if the child passed or failed the screening tests?

Yes 🗆 No 🗆

If yes, please explain \_\_\_\_\_\_

The diagnostic accuracy of hearing tests and cos	st-effectiveness of school entry hea	ring screening programmes ID
Number: DOB:		Postcode:
Would parent(s) like a summary of the pro [Note down preferred contact details]	oject to be sent to them?	Y / N
Referral to Nottingham	a Audiology Services Require	d? Y / N
Name of Child:		
Telephone Number:	Signature of Parent:	
	ts and give them a letter and le CRF and pass to Claire or Shelly	

# INFORMATION SHEET (S1 Cases v1.3 20.09.13)

# The diagnostic accuracy of hearing tests and cost-effectiveness of school entry hearing screening programmes

# Name of Researcher(s): Dr Heather Fortnum, Ms Sam Catterick and Ms Mara Ozolins

#### Invitation

We would like to invite your child to take part in a research study. Before you decide whether you want to do that, it is important for you to understand why the research is being done and what it will involve. If you would like, one of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

#### Why has my child been chosen?

Your child is being invited to take part because we know they have a hearing loss. We are inviting 80 children like your child to take part. We are also inviting 160 children who do not have a hearing loss to take part. Because we know whether or not the children taking part in this study have a hearing loss we can tell if the screening tests we are assessing are able to correctly identify those with and without a hearing loss.

#### Who are the researchers?

The research is being led by Dr Heather Fortnum, an Associate Professor and Reader in Hearing Research at the University of Nottingham. She is working with two research fellows, Sam Catterick and Mara Ozolins who will see the children in this study. The research also involves audiologists in Nottingham and Cambridge, and research methods experts in Exeter.

#### What is the purpose of the study?

Identifying children who have a permanent hearing loss at the earliest possible age is very important. When a hearing loss is detected early, the child's speech and language is usually better and they do better in school. There is now a hearing test at birth for all babies and this means that the vast majority of children born with a hearing loss are identified at birth. However, not all children who will eventually have a hearing loss have that hearing loss at birth.

In most parts of the UK at the moment, children have another hearing test when they start school, using a machine to screen for permanent hearing loss. However, this might not be the best test to use. A new system using a hand-held device to test hearing might be more accurate, and quicker and easier for the children and for the school nurses who do the testing. One aim of this project is to compare two types of hearing tests which can be used in schools to find out which one is better able to identify hearing loss in children.

#### Does my child have to take part?

It is up to you to decide whether or not he or she takes part. If you do decide that your child will take part, you will be asked to sign a consent form. If you later decide that he/she no longer wishes to take part, please inform us and he/she will be withdrawn from the study. You do not need to give a reason and it will not affect the standard of care your child receives.

#### What will happen to my child if they take part?

The research will involve just one session of testing with your child. If your child wears hearing aids, they will be asked to remove these before we test them. We will test your child's hearing with the screening system currently used in schools and with the new handheld device. Each gives out sounds at levels up to the equivalent of a noisy room and your child will need to tell us when they hear a

sound by pressing a button. Each ear will be tested separately. The first system plays the sounds via headphones and the second system plays the sounds from a small machine held next to the child's ear.

We also need to compare the two screening hearing tests with a full test of your child's hearing. This will be done in one of two ways:

- 1. If your child has had a recent hearing test at your local audiology service, or has an appointment for a hearing test in the next 3 months we will just need to access a copy of these results with your permission.
- 2. If they have not had a hearing test in the last 12 months and do not have an appointment to have a hearing test in the next 3 months we would need to do a full hearing test in your local audiology clinic or in the research facility in Nottingham.

### Where will the tests take place?

We will carry out these tests in your own home or at our research facility at Ropewalk House in the centre of Nottingham. You will be able to choose which is most convenient for you. The research session should take no longer than 30 minutes in total and you can be with your child at all times.

### When will my child take part?

The researchers intend to test children just once between December 2012 and October 2014 and your child could be included at any point during this time. Therefore although we would like to know now whether you would like your child to take part, please be aware that you will not be invited for testing until your child is at least 4yrs old.

#### Expenses and payments

We will pay for all your travel expenses to attend for the hearing tests and each child will be offered a book token to the value of  $\pounds$ 20 to say thank you for taking part.

#### What are the possible disadvantages or risks of taking part?

There should be no risk or discomfort for your child. The loudest sound that they will listen to is approximately the equivalent of a noisy room.

#### What are the advantages of taking part?

We cannot promise the study will help your child but the information we get from this study may help to decide how best to detect hearing loss in children in the future.

#### What if I have any concerns?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you are still unhappy and wish to complain formally, you can do this by contacting NHS Complaints <*PALS number for the appropriate hospital to be inserted* >>.

### Will my child taking part in this study be kept confidential?

All information about your child will be handled in confidence.

If your child joins the study, some parts of audiology records and the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. The data may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to your child as a research participant and we will do our best to meet this duty.

All information which is collected about your child during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about your child which leaves the hospital will have your child's name and address removed (anonymised) and a unique code will be used so that they cannot be recognised from it.

Your child's personal data (address, telephone number) will be kept for up to 12 months after the end of the study. All research data will be kept securely for 7 years following publication. After this time your child's data will be disposed of securely. During this time all precautions will be taken by

all those involved to maintain your child's confidentiality; only members of the research team will have access to their personal data.

#### What will happen if I do not want my child to carry on with the study?

Taking part in the study is voluntary and you are free to withdraw your child at any time, without giving any reason, and without their legal rights being affected. If you withdraw your child, then the information collected so far cannot be deleted and this information may still be used in the project analysis.

#### What will happen to the results of the study?

The results of the study will be written up into a report for the National Institute for Health Research who are funding the study. We will also publish the results in academic journals and present the results at academic and clinical conferences. The results will feed into government decisions about the best way to screen for hearing loss in children. We will send you a summary of the results if you would like to receive it.

#### Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the National Institute for Health Research, Health Technology Assessment Programme.

#### Who has reviewed this study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect participant's interests. This study has been reviewed and given favourable opinion by the West Midlands, Staffordshire Research Ethics Committee.

#### Further information and contact details

If you have any questions or would like to talk to someone about this research, please contact either the Chief Investigator, Dr Heather Fortnum or the study researchers, Sam Catterick or Mara Ozolins on 0115 8232600 or email us at SES@nottingham.ac.uk. Alternatively, please write to: Heather Fortnum at the Nottingham Hearing Biomedical Research Unit, Ropewalk House, 113 The Ropewalk, Nottingham, NG1 5DU.

#### Thank you for reading this

# NHS National Institute for Health Research

Nottingham Hearing Biomedical Research Unit Ropewalk House 113 The Ropewalk Nottingham NG1 5DU

Tel: +44 (0) 115 823 2600 Fax: +44 (0) 115 823 2618 Email: nhbru-enquiries@nottingham.ac.uk Web: www.hearIng.nlhr.ac.uk

#### SUMMARY INFORMATION SHEET

(S1 Cases v1.1 20.09.13)

#### Are hearing tests at school accurate and cost effective?

#### What is the study about?

Most children in the UK have a hearing test when they start school. This study will compare different ways of testing hearing to see which is best.

#### Why has my child been chosen?

We are inviting 80 children with a hearing loss (like your child) and 160 children who do not have a hearing loss to take part. We want to see if the hearing tests used can correctly identify those with and without a hearing loss.

#### What will my child have to do?

We will either come to your home or you can come to us at Ropewalk House in the centre of Nottingham. Your child's hearing will be tested using the hearing tests. Each test will play sounds and your child will need to tell us when they hear them by pressing a button. Each ear will be tested separately. The first test plays the sounds over headphones and the second test plays the sounds from a small machine (like a telephone) held next to your child's ear. The research session should take no longer than 30 minutes in total.

#### When will my child take part?

We will test children just once between December 2012 and October 2014.

# What are the advantages of taking part?

The study may not help your child, but the information could help to decide how hearing loss should be tested in children in the future.

# Are there any risks to taking part?

There should be no risk or discomfort or your child. The loudest sound that they will listen to is approximately the equivalent of a noisy room.

# Will my child's information be kept confidential?

All information about your child will be handled in confidence.

### Will we receive any payment?

We will pay for any travel expenses and your child will be given a £20 book token to say thank you.

For further information or contact details of the researchers, please read the detailed information sheet included in this pack.

# If you would like to support the research, please return the reply slip to us in the prepaid envelope provided.

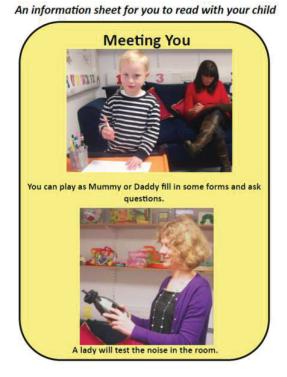
The diagnostic accuracy of hearing tests and cost-effectiveness of school entry hearing screening programmes Summary Information Sheet Study 1 Cases Version 1.1

Date: 20.09.13

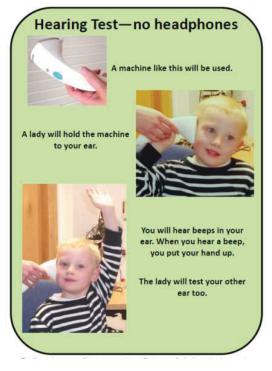
Children's pictorial information sheet for children recruited as cases and seen in the research facility

Page 1

Page 2













The diagnostic accuracy of hearing tests and cost-effectiveness of school entry hearing screening programmes. Children's information sheet. Study 1 controls v1.1 Date 05.12.12



NHS National Institute for Health Research

> Nottingham Hearing Biomedical Research Unit

### INFORMATION SHEET (S1 Controls v1.3: 20.09.13) The diagnostic accuracy of hearing tests and cost-effectiveness of school entry hearing screening programmes

# Name of Researcher(s): Dr Heather Fortnum, Ms Sam Catterick and Ms Mara Ozolins

#### Invitation

We would like to invite your child to take part in a research study. Before you decide whether you want to do that, it is important for you to understand why the research is being done and what it will involve. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

#### Why has my child been chosen?

Your child is being invited to take part because to the best of our knowledge they have normal hearing. We are inviting 160 children like your child to take part. We are also inviting 80 children who do have a hearing loss to take part. Because we know whether or not the children taking part in this study have a hearing loss we can tell if the screening tests we are assessing are able to correctly identify those with and without a hearing loss.

#### Who are the researchers?

The research is being led by Dr Heather Fortnum, an Associate Professor and Reader in Hearing Research at the University of Nottingham. She is working with two research fellows, Sam Catterick and Mara Ozolins who will see the children in this study. The research also involves audiologists in Nottingham and Cambridge, and research methods experts in Exeter.

#### What is the purpose of the study?

Identifying children who have a permanent hearing loss at the earliest possible age is very important. When a hearing loss is detected early, the child's speech and language is usually better and they do better in school. There is now a hearing test at birth for all babies and this means that the vast majority of children born with a hearing loss are identified at birth. However, not all children who will eventually have a hearing loss have that hearing loss at birth.

In most parts of the UK at the moment, children have another hearing test when they start school, using a machine to screen for permanent hearing loss. However, this might not be the best test to use. A new system using a hand-held device to test hearing might be more accurate, and quicker and easier for the children and for the school nurses who do the testing. One aim of this project is to compare two types of hearing tests which can be used in schools to find out which one is better able to identify hearing loss in children.

#### Does my child have to take part?

It is up to you to decide whether or not he or she takes part. If you do decide that your child will take part, you will be asked to sign a consent form. If you later decide that he/she no longer wishes to take part, please inform us and he/she will be withdrawn from the study. You do not need to give a reason and it will not affect the standard of care your child receives.

#### What will happen to my child if they take part?

The research will involve just one session of testing with your child. We will test your child's hearing with the screening system currently used in schools and with the new handheld device. Each gives out sounds at levels up to the equivalent of a noisy room and your child will need to tell us when they hear a sound by pressing a button. Each ear will be tested separately. The first system plays the sounds via headphones and the second system plays the sounds from a small machine held next to the child's ear.

We also need to compare the two screening hearing tests with a full test of your child's hearing. This involves your child listening through headphones to a longer series of tones and indicating to the researcher when they can hear something by moving an object.

#### Where will the tests take place?

We will carry out these tests at our research facility at Ropewalk House in the centre of Nottingham. The research session should take no longer than 45 minutes and you can be with your child at all times.

#### When will my child take part?

The researchers intend to test children just once between December 2012 and October 2014 and your child could be included at any point during this time. Therefore although we would like to know now whether you would like your child to take part, we may not arrange the research appointment straight away.

#### What will happen if you find that my child has a hearing loss?

If the hearing tests indicate that your child might have a hearing loss we will give you a letter explaining that we will refer your child for an appointment at the local audiology clinic to have a further test of their hearing and where you can talk to a hearing specialist.

#### **Expenses and payments**

We will pay for all your travel expenses to attend for the hearing tests and each child will be offered a book token to the value of  $\pm 20$  to say thank you for taking part.

#### What are the possible disadvantages or risks of taking part?

There should be no risk or discomfort for your child. The loudest sound that they will listen to is approximately the equivalent of a noisy room.

#### What are the advantages of taking part?

We cannot promise the study will help your child but the information we get from this study may help to decide how best to detect hearing loss in children in the future.

#### What if I have any concerns?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet. If you are still unhappy and wish to complain formally, you can do this by contacting NHS Complaints on 0800 0153367.

#### Will my child taking part in this study be kept confidential?

All information about your child will be handled in confidence.

The diagnostic accuracy of hearing tests and cost-effectiveness of school entry hearing screening programmes Information Sheet Study 1 controls Version 1.3 Date: 20.09.13

If your child joins the study, some parts of the data collected for the study will be looked at by authorised persons from the University of Nottingham who are organising the research. The data may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to your child as a research participant and we will do our best to meet this duty.

All information which is collected about your child during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about your child which leaves the research facility will have your child's name and address removed (anonymised) and a unique code will be used so that they cannot be recognised from it.

Your child's personal data (address, telephone number) will be kept for up to 12 months after the end of the study. All research data will be kept securely for 7 years following publication. After this time your child's data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your child's confidentiality; only members of the research team will have access to their personal data.

#### What will happen if I do not want my child to carry on with the study?

Taking part in the study is voluntary and you are free to withdraw your child at any time, without giving any reason, and without their legal rights being affected. If you withdraw your child, then the information collected so far cannot be deleted and this information may still be used in the project analysis.

#### What will happen to the results of the study?

The results of the study will be written up into a report for the National Institute for Health Research who are funding the study. We will also publish the results in academic journals and present the results at academic and clinical conferences. The results will feed into government decisions about the best way to screen for hearing loss in children. We will send you a summary of the results if you would like to receive it.

#### Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the National Institute for Health Research, Health Technology Assessment Programme.

#### Who has reviewed this study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect participant's interests. This study has been reviewed and given favourable opinion by the West Midlands, Staffordshire Research Ethics Committee.

#### Further information and contact details

If you have any questions or would like to talk to someone about this research, please contact either the Chief Investigator, Dr Heather Fortnum or the study researchers, Sam Catterick or Mara Ozolins on 0115 8232600 or email us at SES@nottingham.ac.uk. Alternatively, please write to: Heather Fortnum at the Nottingham Hearing Biomedical Research Unit, Ropewalk House, 113 The Ropewalk, Nottingham, NG1 5DU.

#### Thank you for reading this

The diagnostic accuracy of hearing tests and cost-effectiveness of school entry hearing screening programmes Information Sheet Study 1 controls Version 1.3 Date: 20.09.13

# NHS National Institute for Health Research

Nottingham Hearing Biomedical Research Unit

### SUMMARY INFORMATION SHEET (S1 Controls v1.1 20.09.13)

Are hearing tests at school accurate and cost effective?

#### What is the study about?

Most children in the UK have a hearing test when they start school. This study will compare different ways of testing hearing to see which is best.

#### Why has my child been chosen?

We are inviting 80 children with a hearing loss and 160 children who do not have a hearing loss (like your child) to take part. We want to see if the hearing tests used can correctly identify those with and without a hearing loss.

#### What will my child have to do?

Your child's hearing will be tested using two hearing tests. Each test will play sounds and your child will need to tell us when they hear them by pressing a button. Each ear will be tested separately. The first test plays the sounds over headphones and the second test plays the sounds from a small machine (like a telephone) held next to your child's ear.

We also need to compare the two hearing tests with a full test of your child's hearing which involves listening to a longer series of sounds.

The research session should take no longer than 45 minutes in total.

#### When will my child take part?

We will test children at our research unit at Ropewalk House in the centre of Nottingham just once between December 2012 and October 2014.

#### What are the advantages of taking part?

The study may not help your child, but the information could help to decide how hearing loss should be tested in children in the future.

#### Are there any risks to taking part?

There should be no risk or discomfort for your child. The loudest sound that they will listen to is approximately the equivalent of a noisy room.

#### Will my child's information be kept confidential?

All information about your child will be handled in confidence.

#### Will we receive any payment?

We will pay for any travel expenses and your child will be given a £20 book token to say thank you.

# For further information or contact details of the researchers, please read the detailed information sheet included in this pack.

#### If you would like to support the research, please return the reply slip to us in the prepaid envelope provided.

The diagnostic accuracy of hearing tests and cost-effectiveness of school entry hearing screening programmes Summary Information Sheet Study 1 Controls Version 1.1 Date: 20.09.13

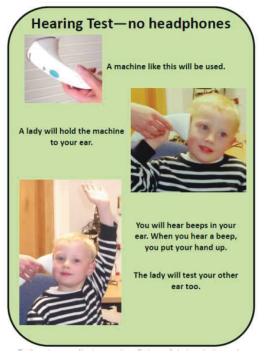
Children's pictorial information sheet for children recruited as controls and seen in the research facility

Page 1

# An information sheet for you to read with your child







Page 2



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