

# Improving behavioural assessment of hearing in babies

## PART A: Babies' reactions to sounds (at-home testing)

### Parental Information Sheet (PIS)

You and your child are being invited to take part in a research study to improve tests of babies' hearing. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding if you wish to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

### About the research

#### *What is the purpose of the research?*

We are interested in how babies respond to different sounds. Our aim is to improve techniques currently used to test hearing in babies. It is vital that we can properly investigate hearing at a young age for children to have the best possible outcomes in cognitive and language development.

Our work will find out what kinds of sounds babies pay most attention to, so that we can get more information about babies' hearing during hearing tests.

#### *Who will conduct the research?*

This research is being led by Dr Anisa Visram and Dr Iain Jackson in the Manchester Centre for Audiology and Deafness (ManCAD; School of Health Sciences, University of Manchester). The wider research team also includes colleagues in the Manchester Centre for Audiology and Deafness, and in the Division of Informatics, Imaging & Data Sciences, both groups at the University of Manchester, as well as collaborators at the Interacoustics Research Unit in Denmark.

#### *Who is funding the research project?*

This project is funded by the William Demant Foundation and receives additional support from the NIHR (National Institute for Health Research) Manchester Biomedical Research Centre (BRC).

#### *What will the outcomes of the research be?*

The data we collect will help us investigate what sorts of sounds babies pay attention and respond to most. This information could help to improve hearing tests for babies.

We plan to present our findings to other researchers and health professionals through publications in academic journals and presentations at conferences.

## **What will my child and I be asked to do if we take part?**

We will send you a document or a link to a webpage which contains several short sound clips (4 seconds long). We ask that you play the sounds to your baby, one at a time, and rate how strong a reaction you see in your baby on a scale from 1 (no reaction) to 5 (strong reaction). Some of the sounds may be familiar to your child (e.g. nursery rhymes or theme tunes), but they have been processed to make them suitable for use in hearing tests... so they might sound a little bit odd!

You can complete the ratings in your own time. You can do it all at once, or over a few sittings if that suits you better. If you have any comments about your child's responses you can also add them for each sound. You can give these responses via an online form, or via a spreadsheet, or on paper: you can discuss with us what suits you best.

You also have the option to send us some audio recordings that you think your child might like (e.g. your voice) which we can add to the list of sounds.

If you are interested, you and your child may be invited to take part in a related study in our hearing labs in Manchester where we test the sounds out for real in a session similar to a baby hearing test.

### ***How long will the study take?***

Before you agree to take part we will take time to talk through the aims and answer any questions you might have (typically by phone or email). The at-home testing can be completed in around 30 minutes.

### ***Where will the research be conducted?***

You will carry out this research in your own home, or other quiet convenient location.

### ***Will I be compensated for taking part?***

Taking part in the study is voluntary, but you will be offered a £10 Amazon voucher to thank you for your time. If you choose to receive a voucher your full name and email address will be shared with our Finance department who will send the voucher to you. Your full name and email address will be securely retained by Finance for a period of up to 7 years for audit purposes only and then destroyed. It will not be used by them for any other purpose.

### ***What happens if my child does not want to take part, or if I change my mind?***

It is up to you to decide whether or not you would like your child to take part. If you decide to take part you will be given a copy of this information sheet to keep and will be asked to sign a consent form.

You are free to withdraw from the study at any time without giving a reason and without detriment to yourself.

It will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

## **Data Protection and Confidentiality**

### ***What information will you collect about me and my child?***

In order to participate in this research project we will need to collect information that could identify you, called “personal identifiable information”. Specifically we will need to collect:

- Your name, and a phone number and/or email address we can contact you on.
- Your child’s name and date of birth.
- Whether your child currently has any issues or difficulties with their hearing or vision, or any significant developmental delay.
- Whether your child has had infections or illnesses that can affect hearing.
- (Optional) Audio recordings you choose to record and send to us.

### **What else do I need to know?**

#### ***Disclosure and Barring Service (DBS) Check***

All members of our team who work with children have undergone relevant Disclosure and Barring Service checks.

#### ***Who has reviewed the research project?***

This project has been reviewed by the University of Manchester Proportionate Research Ethics Committee (reference 2020-10804-17344).

#### ***What should I do if I am concerned about my child’s hearing?***

If you have any concerns about your child’s hearing you should speak to your GP.

The findings of this study might help hearing tests in the future, but in this particular study we are interested only in how babies respond to different sounds. The study is not designed to test for hearing difficulties in individuals, and we will not be able to provide feedback on the performance of any individual child.

### **What if I have a complaint?**

If you have a complaint that you wish to direct to members of the research team you can email them at **bambino@manchester.ac.uk**, or phone on **07785 401460 (Iain Jackson)** or **07543 228 856 (Anisa Visram)**.

**If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact:**

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: [research.complaints@manchester.ac.uk](mailto:research.complaints@manchester.ac.uk) or by telephoning 0161 306 8089

If you wish to contact us about your data protection rights, please email [dataprotection@manchester.ac.uk](mailto:dataprotection@manchester.ac.uk) or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information (by visiting <https://ico.org.uk/make-a-complaint/> or by phone on 0303 123 1113).

## **How we will look after your data**

### ***Under what legal basis are you collecting this information?***

We are collecting and storing this personal identifiable information in accordance with data protection law which protect your rights. These state that we must have a legal basis (a specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

### ***What are my rights in relation to the information you will collect about me?***

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio/video recordings or photographs.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research, which can be found here: <http://documents.manchester.ac.uk/display.aspx?DocID=37095>

### ***Will my and my child's participation in the study be confidential, and will our personal identifiable information be protected?***

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and you can find the full details of how we will look after your data in the section at the end of this information sheet.

It will not be possible to fully anonymise all the data we collect as our video recordings will contain images of participants' faces. However, your child will be assigned a unique ID number at the time the data is collected. Their date of birth will also be replaced with their exact age (i.e. number of days old on the day of the test) meaning no individual can be identified by name or by birth date in our processed dataset.

***How will my data be securely moved and stored?***

The project's electronic data will be stored in a secure internal repository at the University of Manchester and on an encrypted drive held in a locked location at the University of Manchester. Data transfer will take place using encrypted devices and original recordings on the video camera will be deleted. Paper copies of signed consent forms, questionnaires, and any other hand-written forms or notes will also be kept in locked storage.

***What data will be shared outside of the research team?***

Once the project is complete we will submit fully anonymised, processed data to an open access repository (such as the Open Science Framework, [www.osf.io](http://www.osf.io), for example) so that other researchers can also benefit from it and help to speed up new discoveries. This information will be in the form of a simple spreadsheet, and **will not contain any video, images, or any other identifiable information.**

(Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.)

***Who will have access to my and my child's data?***

Only the research team and our collaborators at the Interacoustics Research Unit will have access to the information we collect.

The research team for this project consists of the lead researchers, Dr Anisa Visram and Dr Iain Jackson, and our collaborators in the Manchester Centre for Audiology and Deafness (ManCAD), the Division of Informatics, Imaging & Data Sciences, and the Interacoustics Research Unit.

***What will happen to my data after the project has finished?***

All data and recordings collected from participants, and all paper records, will be retained for 10 years, after which recordings will be deleted and consent forms will be destroyed.

***Will my data be used for future research?***

If interested, you will be given the choice to take part in the next phase of this study, in our hearing labs in Manchester. If you do, we will use the results from this part of the study to help with the second part.

## Contact Details

If you have any queries about the study then please do not hesitate to contact the lead researchers using the project email address **bambino@manchester.ac.uk**, or by phone on **07785 401460 (Iain Jackson)** or **07543 228 856 (Anisa Visram)**.