

## UoM Hearing Health Research Volunteer Database

### Participant Information Sheet (PIS)

Our researchers are part of the Hearing Health theme of the National Institute of Health Research (NIHR) Biomedical Researcher Centre (BRC) in Manchester, and the Manchester Centre for Audiology and Deafness (ManCAD). We have a database of people who are interested in taking part in research related to hearing health. We currently have adults with all levels of hearing on our database.

Before you decide whether to join the Hearing Health Research Volunteer Database, it is important for you to understand why it exists and what joining it will involve. Please take time to read the following information carefully 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. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

### **About the Database**

#### ➤ **What is the purpose of the database?**

We are a multi-disciplinary team with an internationally recognised hearing health research programme that makes a real difference to the lives of people with hearing health needs. However, when we are carrying out research studies, it is sometimes difficult to find enough people to take part. This is especially the case if we have a short period of time to do the research. Also, some research studies need participants to be a certain age or have a particular level of hearing. Having a database of people we can contact quickly means that a research study is more likely to be completed on time and have more meaningful results.

#### ➤ **Do I have to have a hearing problem to be involved?**

No. Sometimes our researchers need people whose hearing thresholds are within the “normal” range to take part in our studies.

#### ➤ **Who manages the Hearing Health Research Volunteer Database?**

The database is managed by Research Audiologists, Helen Whiston and Melanie Lough, along with an administrator (see page 4 for contact details). Researchers from within Manchester BRC and ManCAD are allowed access to a restricted version of the database in order to identify potential participants for their studies (described in more detail on pages 3-4). However, access is only granted by the Research Audiologists once it has been confirmed that the researcher is part of Manchester BRC/ManCAD, and has ethical approval for their particular study.

#### ➤ **Disclosure and Barring Service (DBS) check**

The database managers (Research Audiologists) have undergone satisfactory DBS checks for working with vulnerable adults.

## **Your Involvement**

### **➤ What would I have to do if I joined the volunteer database?**

If you agree to be part of our volunteer database, we will ask you to complete a consent form to say that you have read this information and agree to us contacting you about relevant research studies that you may like to take part in. We will also ask you to complete a short questionnaire about your hearing health. You will be invited to have a standard hearing test, called an audiogram, at the University of Manchester. This would be conducted by a Research Audiologist and would take no more than 30 minutes. This will give us more detailed information about your level of hearing and help researchers to find the appropriate people to invite to participate in their research studies.

### **➤ What happens if you find a problem with my hearing?**

If you are attending for a hearing test and we find something which you didn't know about, the Research Audiologist will discuss it with you and give you a letter to take to your GP or Audiologist.

### **➤ Will I be paid for joining the database?**

You will not be paid for joining the database, however, if you then attend for a research study you will often be reimbursed for your time and refunded reasonable travel expenses.

### **➤ What sort of research will I be invited to take part in?**

Our particular areas of interest include developing new techniques to improve clinical practice as well as endeavouring to gain a better understanding of how we detect, process and make use of sounds. Studies may, for example, involve different types of hearing, listening and balance tests, as well as questionnaires, surveys or opinions.

When you are contacted about a particular study, you will be given information about how you can get involved; there is no obligation to take part if you do not want to.

### **➤ How often will I be contacted?**

This varies depending on how frequently researchers require participants with your characteristics. You may receive a couple of emails within a month, or none for a few months. We aim to email/send you our database newsletter 4 times per year, in order to keep you up-to-date with what projects are ongoing and of the outcome of previous projects that our volunteers have been involved with.

### **➤ What happens if I do not want to take part or if I change my mind?**

It is up to you to decide whether or not to join the Hearing Health Research Volunteer Database. If you do decide to take part after reading this information sheet, you will be asked to sign a consent form (either online or on paper). Once you have decided to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. If you change your mind at any point, and want to be removed from the volunteer database, simply inform the database managers by emailing [hearingresearch@manchester.ac.uk](mailto:hearingresearch@manchester.ac.uk) or by contacting us at the address on page 4.

## **Data Protection and Confidentiality**

### ➤ **What information will you collect about me?**

In order for you to be on the volunteer database, we will need to collect some or all of the following information that could identify you, called “personal identifiable information”:

1. Name, sex, date of birth, and communication requirements.
2. Contact details (e.g. address, email, telephone number), so that we can contact you with research study information and arrange any appointments with you.
3. Details of your hearing level (if tested).
4. Information from the hearing health questionnaire that you have completed, for example, history of tinnitus, balance disorders, and use of any hearing devices.

### ➤ **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 (specific reason) for collecting your data. For the database, 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 your hearing test. This is known as a Subject Access Request. If you would like to know more about your different rights, the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](http://documents.manchester.ac.uk/display.aspx?DocID=37095) (<http://documents.manchester.ac.uk/display.aspx?DocID=37095>).

### ➤ **Will my participation on the database be confidential and my 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 your data will be looked after in the following way:

- The database is stored on a server owned by the University of Manchester. Access to the server is limited within the University IT Services and no data leaves the perimeter of the University.
- The database managers and their administration support have access to all of the above personal information, but this is password-protected.
- Your record on the database will be allocated an ID number as soon as you submit your online form, or as soon as your information is entered onto the electronic database (where application has been on paper).
- Researchers who are granted access to the database by the managers will be able to view your ID number and 3-4 (see above) initially. If you are then identified as a potential participant, the researcher will have access to view your name, date of birth and email address (or other contact). Researcher access to the database is also password-protected.
- Paper copies of hearing test results (where performed), which are anonymised at the time they are recorded, will be kept in a locked filing cabinet for as long as you remain on the database.

- Consent forms (when completed on paper) and receipts of any payment will also be kept in a locked filing cabinet for as long as you remain on the database.
- We aim to contact you every 2 years to ensure you are happy to remain on the database.
- If you decide to come off the database, your online record will be deleted, and your paper hearing test will be disposed of in confidential waste. If, during your time on the database, you consent to participate in a study, the data collected for that study will not be automatically deleted when you are removed from the database. This data is stored and processed separately according to the data management plan for the particular study. You would always be made aware of this prior to giving your consent for a study.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the information 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 project will have a strict duty of confidentiality to you as a research volunteer.

## **Contact Details**

If you have any queries about the database, please contact the database managers (Helen Whiston and Melanie Lough) or the administrator, all of whom are based at the address below:

<p><b>NIHR Manchester Biomedical Research Centre</b>  <b>Manchester Centre for Audiology and Deafness (ManCAD)</b>  <b>School of Health Sciences</b>  <b>Room A4.02 Ellen Wilkinson Building</b>  <b>University of Manchester</b>  <b>Oxford Road</b>  <b>Manchester</b>  <b>M13 9PL</b></p>	<p><b>Tel: 0161 275 0516/0505</b>  <b>Email:</b>  <a href="mailto:hearingresearch@manchester.ac.uk">hearingresearch@manchester.ac.uk</a></p>
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## **Complaints**

If you have a complaint, please contact the database managers using the details above.

If you wish to make a formal complaint to someone independent of the database management team, or if you are not satisfied with the response you have gained from the database managers, then please contact:

The Research Governance and Integrity Officer, 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 275 2674.

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](https://ico.org.uk/concerns) (<https://ico.org.uk/concerns>), tel. 0303 123 1113.

**This Project Has Been Approved by the University of Manchester's Research Ethics Committee  
06/11/17 [Ref: 2017-2815-4078]**