

CONSENT FORM

Study title: Speech recognition and quality of life in Arabic children with OME and the correlation between them

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ERGO number: 68934

Please initial the box(es) if you agree with the statement(s):

<p>I have read and understood the information sheet ((i) participant information_v1_10-11-2021) and have had the opportunity to ask questions about the study.</p> <p>لقد قرأت وفهمت ورقة المعلومات وأتحت لي الفرصة لطرح أسئلة حول الدراسة.</p>	
<p>I agree to take part in this research project and agree for my data to be used for the purpose of this study.</p> <p>أوافق على المشاركة في هذا المشروع البحثي وأوافق على استخدام بياناتي لغرض هذه الدراسة.</p>	
<p>I understand my participation is voluntary and I may withdraw (at any time) for any reason without my participation rights being affected.</p> <p>أنا على أن مشاركتي طوعية ويمكنني الانسحاب (في أي وقت) لأي سبب دون أن تتأثر حقوق المشاركة الخاصة بي.</p>	

Name of participant (print name) اسم المشارك

Signature of participant توقيع المشارك

Date تاريخ

Name of researcher (print name) اسم الباحث

Signature of researcher توقيع الباحث

Date تاريخ

Appendix - Possible additional statements

(Please delete this section before submitting your documents for review).

This is a list of consent statements (in black bold) that you may also wish to use depending on your study type. Guidance is provided in grey italics. This list is not intended to be exhaustive; therefore, please ensure you add any statements necessary for your research. Please copy and paste into the template as appropriate.

General statements

If data cannot be removed you should include an appropriate point regarding this to ensure they have understood e.g.:

I understand that should I withdraw from the study then the information collected about me up to this point may still be used for the purposes of achieving the objectives of the study only.

OR

I understand that if I withdraw from the study that it may not be possible to remove the data once my personal information is no longer linked to the data.

Ensure participants have understood whether they will be identified or not, examples are given below):

I understand that I *will/will not (delete as necessary)* be directly identified in any reports of the research.

OR

I understand that I may be quoted directly in reports of the research but that I will not be directly identified (e.g. that my name will not be used).

OR

I understand that I will be quoted directly in reports of the research and that my name will be used.

Explicit consent should be sought for the use of special category data (i.e. information on ethnicity; sexual orientation; gender identity; religious beliefs; genetic data; biometric data from which you can be uniquely identified; and health data)

Explicit consent should be sought for audio/video recordings or for participation in discussion groups; if anonymity cannot be guaranteed you should seek consent that they have understood this e.g.

I understand that taking part in the study involves audio/video recording *which will be transcribed and then destroyed* for the purposes set out in the participation information sheet. *(delete as appropriate).*

I agree to take part in the *interview/discussion groups/forums* for the purposes set out in the participation information sheet and understand that these will be recorded using *audio/video/written notes. (delete as appropriate).*

I understand that my anonymity cannot be guaranteed in *these discussion forums* but that any information collected by the researchers will be kept confidential and participants will be asked to keep the discussions confidential.

I understand that I must keep the discussions confidential.

I understand that my personal information collected about me such as my name or where I live will not be shared beyond the study team.

I understand that special category information will be collected about me to achieve the objectives of the study (*specify what these are*)

If you wish to use the data for future studies this should be consented for. In the participant information sheet you should provide the following details:

Specify in what form the data will be deposited e.g. anonymised transcripts, audio recordings, survey database etc and if needed repeat the statement for each form of data you plan to hold for future research.

Specify whether the data will be anonymised and how (describe in detail in the PIS)

Specify whether use or access restrictions will apply to the data in the future e.g. exclude commercial use, safeguarded access

An example statement you may use in the consent form is as follows:

I give permission for (*specify the personal information and/or special category data to be stored*) **that I provide to be** *deposited to (name of repository)/ held by (name of researcher/organisation)* **as described in the participant information sheet so it can be used for future research and learning** (*specify broadly the type of research*).

If contact details are being requested to be maintained on a database, consent for this should be sought in a separate consent form with a participant information sheet specific to the use of that contact database. This is because retaining contact details will not fall under the data protection research exemptions. If you require guidance on this, please contact gdpresearch@soton.ac.uk

Clinical Research Statements

I understand my participation is voluntary and that I may withdraw at any time for any reason without my medical care or participation rights being affected.

I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University of Southampton, from regulatory authorities, from the research sponsor or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

I agree to my General Practitioner being informed of my participation in the study.

I understand that the surplus samples of my tissue collected for this study may be stored in a Human Tissue Authority licenced tissue bank for use in future ethically approved research studies.

Tips for Designing a Consent Form

(Please delete this section before submitting your documents for review)

The main features of a good consent form are:

Date and Version number

It is important that the consent form is version numbered and dated so it is possible to track changes if and when they occur.

Use of Ethics reference

This is evidence of ethical approval and will reassure participants – enter the Submission ID generated when you create a submission in ERGO. For Health and Social Care studies that require HRA and/or REC approval, the IRAS reference number should also be included.

Use of itemised statements to allow each component of the research to be agreed to

Information will be commensurate with the study. For example, in an interview study you may want consent to (i) interview and (ii) tape the interview.

Use of Initial boxes

Do not use tick boxes to minimise the risk of fraud or falsification.

Use of participant in other research

If you wish to keep the contact details of the participant to ask them to participate in future studies you should use a separate form for them to give consent, and provide clear instructions on how they can be removed from this contact list at any time. It should be made clear that it is optional and their participation in the research is not dependent on them agreeing to this.

Confirmation of the right to withdraw

You may wish to include a separate statement on confidentiality/anonymity but this is often best explained in the participant information sheet.

Please note that 'withdraw at any time' will only apply to certain types of research. Consider up to what point a participant can withdraw themselves or their data. This should also be detailed in the corresponding information sheet.

Space for printed names, signatures and dates

A space for the name and signature of the person taking consent is also desirable if different from the named researcher.

For studies involving the NHS and social care

For NHS research, extensive guidance notes and exemplars are available on the Health Research Authority (HRA) website:

<http://www.hra-decisiontools.org.uk/consent/>

For studies involving minors

For studies involving minors consent should be sought from the most appropriate proxy, usually a parent/guardian/carer. Consent or assent should also be sought from the minor using a process that is appropriate to the age and capacity of the participant group.

For further advice on the most appropriate method of consent required you can contact your Faculty Ethics Committee or the Research Integrity and Governance Team.

The Health Research Authority (HRA) provide helpful guidance on writing assent forms for children at: <http://www.hra-decisiontools.org.uk/consent/style.html>. Although this is primarily for clinical research many of the points apply to all research involving children.

For studies involving human biological material

Additional consent statements will be required if your project involves collecting human biological material/human tissue. For advice regarding this you can contact the RIG team at rgoinfo@soton.ac.uk, the Tissue Bank Manager or the Designated Individual for the university.

For studies involving adults who lack capacity

A proxy consent form or consultee declaration form should be provided to the most appropriate person to provide proxy consent. This should include a statement to the effect that they believe the participant would have no objection to taking part.

Where possible, the participant should also be given the opportunity to assent or decline to take part in the research. Assent is where the participant directly involved in the research gives confirmation that they are happy to take part, when they are not in position to give informed consent. This must only occur in addition to informed consent. The method and appropriateness of determining this will depend on the participant cohort and research design. You should ensure you comply with the Mental Capacity Act 2005 where appropriate. You can seek further advice from your local Ethics Committee or the Research Governance Office.

The Health Research Authority provide guidance on consent forms for adults lacking capacity in England and Wales at: <http://www.hra-decisiontools.org.uk/consent/examples.html>.

For studies conducted via the internet

For studies taking place on the internet (eg electronic anonymous questionnaires), this consent form may not be the most appropriate method to obtain informed consent. Please follow local guidance on internet based research or contact your Faculty Ethics Committee or the Research Integrity and Governance Team.

The information provided prior to the consent statement should include details of data management including how personal data will be managed. Details of this can be found on the PIS template.

Use of a tick box (for online surveys only)

Most online survey software programmes have an option to allow participants to continue with the survey only if they tick a box giving their consent. This feature should be used at all times. For example, the University of Southampton's online software, iSurvey, uses the following text and tick box:

Please tick (check) this box to indicate that you consent to taking part in this survey.