



## Implemented by Parents And Carers Therapy (IMPACT Trial) Site selection questionnaire

The purpose of this questionnaire is to determine the suitability of your site for this trial. It is not an agreement to conduct the trial. We are interested in your honest assessment. Please consult with other clinicians and support departments before answering the questions. Please ensure you have read the accompanying IMPACT trial summary document before completing this questionnaire.

### Section 1 – General Information

These questions are asked to find out who the **Principal Investigator (PI)** at your site will be, if selected, and their contact details. The PI has overall responsibility at your site, for the conduct of this trial as per the protocol and GCP guidelines, though they can delegate tasks to other trained individuals.

|   |                                      |
|---|--------------------------------------|
| Site name   |                                      |
| Trust name – <i>if applicable and if different from above</i>                                     |                                      |
| Location of where participants will be recruited from, if separate healthcare facility from above | Tick if n/a <input type="checkbox"/> |
| Local R&D contact name and email address  |                                      |
| Name of potential PI  |                                      |
| Job Title of potential PI   |                                      |
| Contact details of potential PI<br>Address<br>Telephone number<br>Email address                   |                                      |

### Section 2 – Clinical Trial Experience

|  |  |
|--|--|
| Does the potential PI have a current (within last 2 years) GCP certificate?                                  | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| Has the potential PI been a PI previously?   | <input type="checkbox"/> Yes <input type="checkbox"/> No   |
| If yes, what kind of trials were they a PI on?<br><br><i>Tick all that apply</i>                             | <input type="checkbox"/> CTIMP (drug)<br><input type="checkbox"/> Medical device<br><input type="checkbox"/> Complex intervention<br><input type="checkbox"/> n/a (not been a PI before) |
| If the potential PI has not worked as a PI before, please state their previous experience in clinical trials |  |

### Section 3 – Site Capacity

|  |  |
|--|--|
| Is the potential PI involved in any other clinical trials in the same or a similar participant population currently? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If yes to the above, please provide details  |  |

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|   |  |
|---|--|
| Is there someone available at the site to undertake the role of PI in the event of the PI leaving or taking an extended leave of absence? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If yes to the above, please give their name/role and contact details  |  |

Section 4 – Research Staff support

Please provide details of research staff who may work on the trial at your site, supporting research activities if selected, and give details of their research experience (trial recruitment due to start June 2025 and continue over 26 months).

| Name | Role (e.g., research nurse, pharmacist, radiographer, etc) | Email Address | Experience   | Funding   |
|------|--|---------------|--|---|
|      |  |               | <input type="checkbox"/> <1 year<br><input type="checkbox"/> 1-3years<br><input type="checkbox"/> >3 years | <input type="checkbox"/> CRN<br><input type="checkbox"/> Trust / Dept<br><input type="checkbox"/> Other |
|      |  |               | <input type="checkbox"/> <1 year<br><input type="checkbox"/> 1-3years<br><input type="checkbox"/> >3 years | <input type="checkbox"/> CRN<br><input type="checkbox"/> Trust / Dept<br><input type="checkbox"/> Other |
|      |  |               | <input type="checkbox"/> <1 year<br><input type="checkbox"/> 1-3years<br><input type="checkbox"/> >3 years | <input type="checkbox"/> CRN<br><input type="checkbox"/> Trust / Dept<br><input type="checkbox"/> Other |
|      |  |               | <input type="checkbox"/> <1 year<br><input type="checkbox"/> 1-3years<br><input type="checkbox"/> >3 years | <input type="checkbox"/> CRN<br><input type="checkbox"/> Trust / Dept<br><input type="checkbox"/> Other |

|   |  |
|---|--|
| Can the taking of informed consent in clinical trials be delegated to any of the above-named roles in your Trust?                       | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure |
| Do you have access to dedicated research staff time for the duration of this trial e.g. for completion of data entry?                   | <input type="checkbox"/> Yes <input type="checkbox"/> No                                 |
| Are there appropriately trained staff at site to complete the Pre-School Language Scale – fifth edition UK (PLS-5 UK) trial assessment? | <input type="checkbox"/> Yes <input type="checkbox"/> No                                 |

Section 5 – Equipment and Facilities

|   |  |
|---|--|
| Do you have a computer/laptop available for data entry?                     | <input type="checkbox"/> Yes <input type="checkbox"/> No                                 |
| Do your research team have experience of electronic data entry (i.e. eCRF)? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure |

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|   |   |
|---|---|
| If yes to the above, have they used a database system called <b>REDCAP</b> ?              | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure  |
| Do you have <b>archiving facilities</b> at your Trust for trial documentation for 7 years | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure  |
| If no, are off-site facilities used   | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unsure  |
| What language <b>translation facilities</b> are available at site for parents?            | <input type="checkbox"/> Professional Translators<br><input type="checkbox"/> PALS<br><input type="checkbox"/> None<br><input type="checkbox"/> Other (please specify): |

**Section 6 – Trial Population**

|   |  |
|---|--|
| Approximately how many children aged <b>5 or under</b> receive cochlear implants per year?  |  |
| Of those children, approximately how many may be suitable to be <b>recruited</b> into the trial per year?                             |  |
| Are there <b>potential challenges</b> with identifying children who meet the <b>trial criteria</b> ?                                  |  |
| Do you anticipate any <b>concerns with recruitment</b> , particularly regarding parent engagement?<br>If yes, please provide details. | <input type="checkbox"/> Yes <input type="checkbox"/> No |

**Section 7 – Current practice**

This section is to understand what current practice looks like at your site for children aged from birth to 5 years who will have cochlear implantation surgery, from CI suitability to post-implantation. The below focuses on SLT rehab appointments and outcomes.

|   |   |
|---|---|
| Do you currently use any formal <b>parent-implemented programmes</b> as part of CI rehabilitation? If yes, please describe. | <input type="checkbox"/> Yes <input type="checkbox"/> No  |
| Do you signpost parents to programmes?  | <input type="checkbox"/> Audio Verbal UK (AVUK)<br><input type="checkbox"/> The Elizabeth Foundation<br><input type="checkbox"/> No<br><input type="checkbox"/> Other (please specify): |
| Is the Preschool Language Scale ( <b>PLS-5 UK</b> ) used for <b>CI suitability assessment</b> at your site?                 | <input type="checkbox"/> Yes <input type="checkbox"/> No  |
| If PLS-5 is used in assessment, who usually completes this?   | <input type="checkbox"/> Site SLT<br><input type="checkbox"/> Community SLT<br><input type="checkbox"/> Teacher of the Deaf<br><input type="checkbox"/> Other (please specify):         |

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|   |  |
|---|--|
| <b>Document Title:</b> Site Selection Questionnaire |  |
| <b>Trial Name:</b> IMPACT                           |  |
| <b>Version No:</b> 2.0                              |  |
| <b>Version Date:</b> 17 Nov 2025                    |  |



|  |  |
|--|--|
| <p>Please briefly describe any <b>rehabilitation</b> that children under 5 receive <b>as standard</b> at your site:<br/><i>(Please include details of assessment tools used for language development, child behaviour, development and social-emotional functioning, parent-child interaction development, time points when children are seen face-to-face, healthcare professionals involved and their roles)</i></p> |  |
| <p>To <b>participate</b> in the IMPACT trial would it be feasible for you to <b>amend the timing of PLS-5</b> completion in line with the trial requirements?<br/><i>(1x at baseline after consenting to the trial prior to surgery, 1x 6-months post-randomisation and 1x 12-months post-randomisation)</i></p>   |  |

**Section 8 – Summary**

|   |   |
|---|---|
| <p>Using the information provided, could your site support <b>all</b> requirements for this trial?</p>  | <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> |
| <p>If no, please give details of the areas you are <b>unable</b> to support. <i>We may be able to provide solutions to some barriers.</i></p> |   |
| <p>Please provide any additional information you feel is relevant to support your participation in the trial</p>                              |   |

**Thank you for taking the time to complete this questionnaire. Once completed, please send to [impactstudy@nottingham.ac.uk](mailto:impactstudy@nottingham.ac.uk)**

**If you have any questions, then please do not hesitate to contact the IMPACT team at the same email address or by calling 01158 231587**

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|                        |                              |
|------------------------|------------------------------|
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