

North West - Greater Manchester East Research Ethics Committee

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**Please note: This is an
acknowledgement letter from
the REC only and does not
allow you to start your study
at NHS sites in England until
you receive HRA Approval**

07 October 2019

Professor Anne Schilder
NIHR Research Professor
evidENT Team - Ear Institute University College London
330 Grays Inn Road
Kings Cross
London
WC1X 8DA

Dear Professor Schilder

Study title:	Prognostic factors for outcomes of idiopathic Sudden onset Sensorineural Hearing Loss: the SeaSheL national prospective cohort study
REC reference:	19/NW/0556
Protocol number:	124643
IRAS project ID:	258494

Thank you for your letter of 24 September 2019. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 05 September 2019

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants	1.0	23 September 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [2019-2020]		
Non-validated questionnaire [Hearing Handicap Inventory Elderly]	1.1	14 September 2019
Non-validated questionnaire [Hearing Handicap Inventory Adults]	1.1	14 September 2019
Participant consent form	1.1	14 September 2019
Participant information sheet (PIS)	1.1	14 September 2019

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

19/NW/0556	Please quote this number on all correspondence
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Yours sincerely



Amber Ecclestone
Approvals Specialist

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Copy to: *Mr Rishi Mandavia, UCL Ear Institute*
Mr Cameron Berg, University College London Joint Research Office