North West - Greater Manchester East Research Ethics Committee
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ
Telephone: 0207 104 8196

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

05 September 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**

The Proportionate Review Sub-committee of the North West - Greater Manchester East Research Ethics Committee reviewed the above application on 28 August 2019.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation,

subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Action required by the applicant;

Number	Condition
1.	The following changes/revisions should be made to the Participant Information Sheets and Consent Forms: 1.1 The PR Sub-Committee requested that the address at UCL should be placed at the bottom right end of the Participant Information Sheet. 1.2 In the National Hearing Handicap Inventory form, the PR Sub-Committee acknowledged that the numbers under the words “yes or sometimes or no” were for scoring but requested that they should be removed because they may be somewhat confusing for the participants as well as misleading and could skew the results. 1.3 The PR Sub-Committee requested that the boxes in the Consent Form should be initialled and not ticked. The PR Sub-Committee also requested that a line should be included in the Consent Form for the researcher to sign and print their name. 1.4 In point 5 of the Consent Form, the PR Sub-Committee did not agree with the wording and requested that it should be made clear that the use of the participant’s information from this study in another study was optional. 1.5 The PR Sub-Committee further requested that the standard regulatory clause should be included in the consent form.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given

permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

It is a condition of the REC favourable opinion that all clinical trials are registered on a publicly accessible database. For this purpose, clinical trials are defined as the first four project categories in IRAS project filter question 2. For clinical trials of investigational medicinal products (CTIMPs), other than adult phase I trials, registration is a legal requirement.

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We routinely audit applications for compliance with these conditions.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators

- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*	
Covering letter on headed paper [Cover letter]		01 August 2019	
Evidence of Sponsor insurance or indemnity (non-NHS Sponsors only) [Sponsor Indemnity]			
IRAS Application Form [IRAS_Form_02082019]		02 August 2019	
Letter from funder [SeaSHeL, Letter of funding, dated 20 May 2019, IRAS 258494]		20 May 2019	
Letter from sponsor [Sponsorship]		15 July 2019	
Letter from statistician [Letter statistics involvement]		16 July 2019	
Participant consent form [Consent Form]	1.0	11 June 2019	
Participant information sheet (PIS) [Participant Information Sheet]	1.0	11 June 2019	
Referee's report or other scientific critique report [External review SeaSHeL]		11 April 2019	
Referee's report or other scientific critique report [External review SeaSHeL 2]		12 April 2019	
Research protocol or project proposal [SeaSHeL, Study Protocol, Version 1.0, dated 05 Feb 2019, IRAS 258494]	1.0	05 February 2019	
Summary CV for Chief Investigator (CI) [SeaSHeL, Summary CV CI]			
Validated questionnaire [SeaSHeL, Health Utilities Mark 3, version 1.0, dated 25th June 2019, IRAS 258484]	1.0	25 June 2019	
Validated questionnaire [SeaSHeL, Hearing Handicap Inventory for Elderly, version 1.0, dated 25th June 2019, IRAS 258484]	1.0	25 June 2019	
Validated questionnaire [SeaSHeL, Hearing Handicap Inventory for Adults, version 1.0, dated 25th June 2019, IRAS 258494]	1.0	25 June 2019	

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

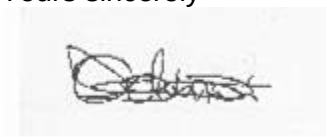
HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

With the Committee's best wishes for the success of this project.

19/NW/0556	**Please quote this number on all correspondence**

Yours sincerely



Signed on behalf of;
Mr Simon Jones
Chair

Email: nrescommittee.northwest-gmeast@nhs.net

Enclosures:	List of names and professions of members who took part in the review
	"After ethical review – guidance for researchers"
Copy to:	Mr Rishi Mandavia, UCL Ear Institute

North West - Greater Manchester East Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 28 August 2019

Committee Members:

Name	*Profession*	*Present*	*Notes*	
Mr James Burns	Retired	Yes		
Miss Isabelle Butcher	PhD Researcher	Yes		
Mr Simon Jones	Podiatrist	Yes	Chair	

Also in attendance:

Name	*Position (or reason for attending)*	
Miss Damilola Odunlami	Approvals Officer	