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07 October 2019

Dear Professor Schilder

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Prognostic factors for outcomes of idiopathic Sudden onset Sensorineural Hearing Loss: the SeaSHeL national prospective cohort study**
IRAS project ID:	**258494**
Protocol number:	**124643**
REC reference:	**19/NW/0556**
Sponsor	**University College of London Hospital Trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **258494**. Please quote this on all correspondence.

Yours sincerely,
Amber Ecclestone

Approvals Specialist

Email: hra.approval@nhs.net

Copy to: *Mr Rishi Mandavia, UCL Ear Institute*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Copies of advertisement materials for research participants	1.0	23 September 2019
Covering letter on headed paper [Cover letter]		01 August 2019
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [2019-2020]		
HRA Schedule of Events [20 sites]		
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
Non-validated questionnaire [Hearing Handicap Inventory Elderly]	1.1	14 September 2019
Non-validated questionnaire [Hearing Handicap Inventory Adults]	1.1	14 September 2019
Organisation Information Document [20 sites]		
Organisation Information Document [77 sites]		
Participant consent form	1.1	14 September 2019
Participant information sheet (PIS)	1.1	14 September 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
Schedule of Events or SoECAT [77 sites]		
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

IRAS project ID	258494

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Multiple site types There are two sitetypes participating in the study Site Type 1 and Site Type 2. Site Type 1 – Data collection Site Type 2 – Questionnaire cohort	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	It is noted this this study has requested inclusion on the CRN portfolio but does not incur Excess Treatment Costs. The researchers have nonetheless provided an AcoRD specialist authorised SoECAT.	**Data collection cohort** TheChief Investigator will be responsible for all research activities performed atstudy sites. **Questionnaire cohort** APrincipal Investigator should be appointed at study sites.	**Data collection cohort** Useof identifiable patient records held by an NHS organisation to identifypotential participants should be undertaken by a member of the direct care teamfor the patient, so it would not normally be acceptable for this to be done bystaff not employed by that organisation. **Questionnaire cohort** NoHonorary Research Contracts, Letters of Access or pre-engagement checks areexpected for local staff employed by the participating NHS organisations. Wherearrangements are not already in place, research staff

					not employed by the NHShost organisation undertaking any of the research activities listed in theresearch application would be expected to obtain a Letter of Access based onstandard DBS checks and occupational health clearance.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they do intend to apply for inclusion on the NIHR CRN Portfolio.