

22 August 2023

Professor Andreas Brunklaus
Consultant Paediatric Neurologist
NHS Greater Glasgow and Clyde
Royal Hospital for Children
Fraser of Allander Neurosciences Unit, Level 0, Zone 1, Office Block
1345 Govan Road, Glasgow, UK
G51 4TF

Dear Professor Brunklaus,

Study title:	SCN1A Horizons: A natural history study of SCN1A-related epilepsies in the United Kingdom
REC reference:	22/SS/0072
Protocol number:	N/A
Amendment number:	SA 03
Amendment date:	01 August 2023
IRAS project ID:	316675

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The Sub-Committee noted that the PIS documents related to Personal Consultee and Nominated Consultee were not applicable for Scotland A REC review, so both of clean and tracked version of the documents were not in the below documents list. There was a little pronoun typo regarding GP notification in the PISs and Committee members requested to update them. The updated documents were sent back for further review.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee had no further concerns regarding the amendment.

Headquarters
Waverley Gate
2-4 Waterloo Place
Edinburgh EH1 3EG

Interim Chair Esther Robertson
Chief Executive Calum Campbell
*Lothian NHS Board is the common
name of Lothian Health Board*

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [SA 03 locked amendment tool]	1.6	01 August 2023
Other [Data Protection Impact Assessment]	3.3	28 July 2023
Other [Protocol Summary of Changes]	2.0	01 August 2023
Participant information sheet (PIS) [Participant PIS ICF - Clean]	2.0	01 August 2023
Participant information sheet (PIS) [Participant PIS ICF - Tracked]	2.0	01 August 2023
Participant information sheet (PIS) [PIS ICF Parent_Legal Guardian v2.0 010823 CLEAN]	2.0	01 August 2023
Participant information sheet (PIS) [PIS ICF Parent_Legal Guardian v2.0 010823 TRACKED]	2.0	01 August 2023
Participant information sheet (PIS) [PIS ICF WG.WA.NR v2.0 010823 CLEAN]	2.0	01 August 2023
Participant information sheet (PIS) [PIS ICF WG.WA.NR v2.0 010823 TRACKED]	2.0	01 August 2023
Research protocol or project proposal [Protocol - Clean]	2.0	01 August 2023
Research protocol or project proposal [Protocol - Tracked]	2.0	01 August 2023

Membership of the Committee

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

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

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.

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/>

IRAS Project ID - 316675:	Please quote this number on all correspondence
----------------------------------	---

Yours sincerely,



Dr Mary-Joan Macleod
Chair

E-mail: Sriparna.Pal@nhslothian.scot.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Pamela Sandu

Scotland A: Adults with Incapacity only

Attendance at Sub-Committee of the REC meeting on 11 August 2023

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Anne Forster	Retired Product Development Manager (Standard Life)	Yes	
Dr Mary-Joan Macleod	Clinical Pharmacologist/Consultant Physician	Yes	
Dr Lindsay Ramage	Director of Policy, Systems & Performance, Research & Innovation Services	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Manx Neill	Scotland A/B REC Manager
Mrs Sriparna Pal	Administrative Assistant-Scotland A REC