Scotland A Research Ethics Committee

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15 April 2016

Professor Sameer Zuberi
Fraser of Allander Neurosciences Unit
Royal Hospital for Children
1345 Govan Road
G514TF

Dear Professor Zuberi

Study title:	**Can stratification of childhood epilepsy through detailed phenotyping and whole genome sequencing identify novel genetic aetiologies and genetic modifiers of treatment response?**
REC reference:	**16/SS/0054**
Protocol number:	**GN15NE178**
IRAS project ID:	**170749**

Thank you for your letter, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.
We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Miss Manx Neill, manx.neill@nhslothian.scot.nhs.uk.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Adults with Incapacity (Scotland) Act 2000
I confirm that the Committee has approved this research project for the purposes of the Adults with Incapacity (Scotland) Act 2000. The Committee is satisfied that the requirements of section 51 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Conditions of the favourable opinion

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

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission 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 NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

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

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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).

Ethical review of research sites

NHS 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" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter to REC panel April 5th]	1.0	08 April 2016
GP/consultant information sheets or letters [GP Letter]	1.1	04 April 2016
GP/consultant information sheets or letters [Managing Clinician Letter]	1.1	04 April 2016
Letters of invitation to participant [Gene Discovery]	1.1	04 April 2016
Letters of invitation to participant [SCN1A]	1.1	04 April 2016
Letters of invitation to participant [Clinician_SCN1A]	1.1	04 April 2016
Letters of invitation to participant [Clinician_Gene Discovery]	1.1	04 April 2016
Non-validated questionnaire [SCN1A Data Collection]	1.1	04 April 2016
Non-validated questionnaire [Experience Questionnaire_Clinician]	1.1	04 April 2016
Non-validated questionnaire [Experience Questionnaire_Parent/Carer]	1.1	04 April 2016

Non-validated questionnaire [Expectations Questionaire_Parent/Carer]	1.1	04 April 2016
Participant consent form [Adult]	1.1	04 April 2016
Participant consent form [Parent_Skin Biopsy]	1.1	04 April 2016
Participant consent form [Parent]	1.1	04 April 2016
Participant consent form [Parent_Trio]	1.1	04 April 2016
Participant consent form [Young Person Assent]	1.1	04 April 2016
Participant consent form [Young Person_Skin Biopsy]	1.1	04 April 2016
Participant consent form [Young Person]	1.1	04 April 2016
Participant consent form [Adult With Incapacity]	1.2	04 April 2016
Participant information sheet (PIS) [Child]	1.1	04 April 2016
Participant information sheet (PIS) [Adult]	1.1	04 April 2016
Participant information sheet (PIS) [Parent]	1.1	04 April 2016
Participant information sheet (PIS) [Welfare Guardian]	1.2	04 April 2016
Participant information sheet (PIS) [Young Person]	1.1	04 April 2016
REC Application Form [REC_Form_12042016]		12 April 2016
Research protocol or project proposal [SCN1A Data Collection Form]	1.1	04 April 2016
Summary CV for Chief Investigator (CI) [Sameeer Zuberi CV]		12 February 2016
Summary CV for student [Joseph Symonds CV]		12 February 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Study Protocol]	1.1	04 April 2016

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.

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

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

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/

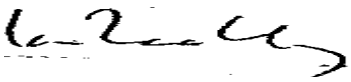
HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/SS/0054	**Please quote this number on all correspondence**

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

Yours sincerely



Dr Ian Zealley
Chair

Email:manx.neill@nhslothian.scot.nhs.uk

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: *Ms Leigh Hamilton*
Dr Paul Dearie, NHS Greater Glasgow and Clyde Research and Development