Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Alasdair parker
Consultant Paediatric Neurologist
Eden House
48, Eden Street,
CAMBRIDGE
CB1 1EL

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

19 October 2022

Dear Dr Parker

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

Study title:	**Investigation into the presentation, diagnosis and management of congenital in sensitivity to pain – a surveillance study**
IRAS project ID:	**282740**
REC reference:	**21/PR/1064**
Sponsor	**Cambridge University Hospitals NHS Foundation 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 **282740**. Please quote this on all correspondence.

Yours sincerely,

Carolyn Halliwell

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Dr Jonathan Alvarez Olieff, Cambridge University Hospitals*

List of Documents

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

Document	*Version*	*Date*
Covering letter on headed paper [Response to queries]	1.1	16 March 2022
GP/consultant information sheets or letters [Info sheet CPN]	1.1	17 February 2022
GP/consultant information sheets or letters [Case notitification]	1.3	28 July 2022
IRAS Application Form [IRAS_Form_07032022]		07 March 2022
Other [oras reply 30 7 22]		30 July 2022
Participant consent form [Assent Form CIP 6-11]	1.2	08 June 2022
Participant consent form [CIP consent 16 and 17 years]	1.2	08 June 2022
Participant consent form [Consent Form CIP Parents]	1.2	08 June 2022
Participant consent form [assent 12-15]	1.4	28 September 2022
Participant information sheet (PIS) [PIS CIP 6-11]	1.1	05 April 2022
Participant information sheet (PIS) [Assent Form CIP 6-11]	1.2	08 June 2022
Participant information sheet (PIS) [Assent Form CIP 12-15]	1.2	08 June 2022
Participant information sheet (PIS) [cip info 12-15]	1.4	28 September 2022
Participant information sheet (PIS) [CIP info sheet 16 and 17 years]	1.4	28 September 2022
Participant information sheet (PIS) [CIP info sheet families]	1.4	28 September 2022
Research protocol or project proposal [Protoco]	1.4	28 September 2022
Summary CV for Chief Investigator (CI) [CV A Parker 2019]	1.0	16 August 2020

IRAS project ID	282740

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
All sites will be undertaking the same activities therefore there is only one site type.	The single participating NHS organisation of this type is also sponsoring the research. You should work with your sponsor R&D office to make arrangements to set up the study. The sponsor R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.	This is a single site study sponsored by the participating NHS organisation therefore no agreements are expected.	No Organisation Information Document has been provided and so relevant conversations should be held with between the research team and the relevant R&D office to understand study funding arrangements.	In line with HRA/HCRW expectations a Principal Investigator should be appointed at participating NHS organisations of this type.	Where an external individual will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold a Letter of Access. This should be issued be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm Occupational Health Clearance These should confirm standard DBS checks

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 not intend to apply for inclusion on the NIHR CRN Portfolio The applicants will identify potential participants via the British Paediatric Neurology surveillance unit (BPNSU) acting as a data collection centre.