



North East - Newcastle & North Tyneside 1 Research Ethics Committee

NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

02 February 2023

Dr Sam Amin
University Hospitals Bristol and Weston NHS Foundation Trust
Department of Paediatric Neurology, Bristol Royal Hospital for Children
Level 6 Education and Research Centre
Upper Maudlin Street, Bristol
BS2 8AE

Dear Dr Amin,

Title of the Research Database:	Research Database for CDKL5 Deficiency Disorder UK
REC reference:	23/NE/0010
IRAS project ID:	296944

Thank you for your letter of 25th January 2023 which responded to the Committee's request for further information on the above research database and thank you for the submission of revised documentation.

The further information has been considered on behalf of the Committee by the Chair together with the Vice-Chair.

Confirmation of ethical opinion

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

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/>

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

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 haven't 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. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: <https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/>

Duration of ethical opinion

The favourable opinion is given for a period of five years from the date of this letter provided that you comply with the standard conditions of ethical approval for Research Databases set out in the attached document. You are advised to study the conditions carefully. The opinion may be renewed for a further period of up to five years on receipt of a fresh application. It is suggested that the fresh application is made 3-6 months before the 5 years expires, to ensure continuous approval for the research database.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [IRAS Covering Letter]		
Covering letter on headed paper [Covering Letter for CDKL5 Research Database v 2]	2	23 January 2023
IRAS Checklist XML [Checklist_23012023]		23 January 2023
IRAS Checklist XML [Checklist_25012023]		25 January 2023
Other [CONSULTEE INFORMATION SHEET FOR PARENTS/CARERS]	v1	03 January 2023
Other [CONSULTEE DECLARATION FORM FOR PARENTS/GUARDIANS/ CARERS]	v1	03 January 2023
Other [CV Dr Sam Amin]		05 January 2023
Other [Patient Consent Form]	v.2	23 January 2023
Other [CDKL5 Patient Database Protocol]	v.2	23 January 2023
Other [Covering Letter]	v.2	23 January 2023
Other [Consultee Information Sheet]	v.3	24 January 2023
Other [Consultee Declaration Form]	v.3	24 January 2023
Other [Response to Provisional Opinion by REC]	v.1	25 January 2023
Participant consent form [CONSENT FORM]	v1	25 November 2022
Participant information sheet (PIS) [PARTICIPANT INFORMATION SHEET]	v1	25 November 2022
Protocol for management of the database [PROTOCOL]	0.2	25 November 2022
REC Application Form [RD_Form_04012023]		04 January 2023

Research governance

Under the UK Policy Framework for Health and Social Care Research, there is no requirement for NHS research permission for the establishment of research databases in the NHS. Applications to NHS R&D offices through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the database.

Research permission is also not required by collaborators at data collection centres (DCCs) who provide data under the terms of a supply agreement between the organisation and the database. DCCs are not research sites for the purposes of the RGF.

Database managers are advised to provide R&D offices at all DCCs with a copy of the REC application for information, together with a copy of the favourable opinion letter when available. All DCCs should be listed in Part C of the REC application.

NHS researchers undertaking specific research projects using data supplied by a database must apply for permission to R&D offices at all organisations where the research is conducted, whether or not the database has ethical approval.

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 standard conditions give detailed guidance on reporting requirements for research databases with a favourable opinion, including:

- Notifying substantial amendments
- Submitting Annual Progress reports

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 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/>

Yours sincerely,

pp. Miss Roma McGeehan

Mr Paddy Stevenson
Chair

newcastlenorthtyneside1.rec@hra.nhs.uk

Enclosures: (RD) Conditions of Approval

[Research Database – Conditions of Approval](#)

Copy to: Dr Sam Amin University Hospitals Bristol and Weston NHS Foundation
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