South Central - Hampshire A Research Ethics Committee
Health Research Authority
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Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

21 January 2026

Dr Sithara Ramdas
Consultant Paediatric Neurologist
OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST
JOHN RADCLIFFE HOSPITAL
HEADLEY WAY
HEADINGTON OXFORD
OX3 9DU

Dear Dr Ramdas

Study title:	**Prospective and retrospective study of clinical features and outcomes of critical illness polyneuropathy and/or myopathy in children and young people, Version 2**
REC reference:	**25/SC/0395**
Protocol number:	**Not Applicable**
IRAS project ID:	**358225**

Thank you for your letter of 16 January 2026, responding to the Research Ethics Committee's (REC) 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 Alternate Vice Chair, Katie Meadmore and Olga Kozlowska.

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.

Mental Capacity Act 2005 (England and Wales)

The committee did not approve this research project for the purposes of the Mental Capacity Act 2005 (England and Wales). The research may not be carried out on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Mental Capacity Act (Northern Ireland) 2016

The Committee did not approve this research project for the purposes of Part 8 of the Mental Capacity Act (Northern Ireland 2016). The research may not be carried out on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Relevance of the research to the impairing condition

The Committee asked the applicant for the justification for including Adults Lacking Capacity in the Study. From the documentation submitted the Committee was unable to determine what proportion of participants who might join the research had lacked capacity. It was thought the justification was around cognitive impairment, but this was not an exclusion criterion. The Mental Capacity Act gives clear guidance around what was and was not appropriate. For example, has the individual the capacity to make decisions for themselves. The applicant stated they did not want to exclude patients who lacked capacity from the study as these potential participants did come into clinics and would be an important element of the data they could potentially collect. They also had patients who had learning disabilities that they were keen not to exclude under this heading. To exclude them might result in losing some important research information. It would also benefit the collection of Standard of Care (SoC) information. The Committee considered that the research was not connected with an impairing condition affecting persons lacking capacity or the treatment of the condition.

Justification for including adults lacking capacity to meet the research objectives

The Committee asked the applicant if participants may lose capacity to consent once in the study. The applicant stated this was unlikely to happen as this condition does not affect the brain. The applicant stated that potential participants who lacked capacity would be dealing with a pre critical mental disability that was not caused by polyneuropathy. The Committee asked the applicant why they need to include these participants. The applicant confirmed they would only be included for patient population information only. The Committee stated that when including

adults who lacked capacity being involved in the study, the applicant needs to show clear reason for including them in the study to comply with the Mental Capacity Act. The applicant stated that as this research was conducted for the first time, this research it could not currently be evidenced under the Mental Capacity Act. It was suggested that a separate study could be done after the current research to allow evidence from those who lacked capacity to consent. The MCA Its designed for those people who lacked capacity, not those with mental disabilities or learning disabilities. The Committee stated they would write to the applicant with further their decision. The Committee considered that the research could be carried out equally effectively if it was confined to participants able to give consent.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

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

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) 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 HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

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 research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a public registry before the first participant is recruited and no later than six weeks after. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

A 'public registry' means any registry on the WHO list of primary registries or the ICMJE list of registries provided the registry facilitates public access to information about the UK trial.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

Where a deferral is agreed we expect the sponsor to publish a minimal record on a publicly accessible registry. When the deferral period ends, the sponsor should publish the full record on the same registry, to fulfil the condition of the REC favourable opinion.

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Where the study is registered on ClinicalTrials.gov, please inform deferrals@hra.nhs.uk and the Research Ethics Committee (REC) which issued the final ethical opinion so that our records can be updated.

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. Where a deferral is agreed, a minimum research summary will still be published in the research summaries database. At the end of the deferral period, we will publish the full research summary.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: Research summaries - Health Research Authority (hra.nhs.uk)

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).

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, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at Managing your approval - Health Research Authority (hra.nhs.uk)

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) 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/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

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

Document	*Version*	*Date*
Covering letter on headed paper [Cover Letter]		12 November 2025
IRAS Application Form [IRAS_Form_14112025]		14 November 2025
Letter from funder [Funding Letter]		04 March 2025
Letter from sponsor [Sponsorship letter]		06 November 2025
Other [Participant Contact Information Sheet]	1.0	05 November 2025
Other [Participant Contact Information Sheet]	V1.1	07 January 2026
Other [Response Letter to REC]	NA	07 January 2026
Participant consent form [Parent/Guardian Consent Form]	1.0	05 November 2025
Participant consent form [Consultee Declaration Form]	1.0	05 November 2025
Participant consent form [16+ Consent Form]	1.0	05 November 2025
Participant consent form [Assent Form]	1.0	05 November 2025
Participant information sheet (PIS) [Parent/ Guardian PIS]	V1.1 TC	07 January 2026
Participant information sheet (PIS) [16+ PIS]	V1.1	07 January 2026
Participant information sheet (PIS) [11-15yrs PIS]	V1.1	07 January 2026
Participant information sheet (PIS) [6-10yrs PIS]	V1.1	07 January 2026
Participant information sheet (PIS) [3a. 16+ PIS V1.1 07Jan2026 TC]	1.1	07 January 2026
Participant information sheet (PIS) [4a. 11-15 PIS V1.1 07Jan2026 TC]	1.1	07 January 2025

Participant information sheet (PIS) [5a. 6-10 PIS V1.1 07Jan2026 TC]	1.1	07 January 2026
Participant information sheet (PIS) [10a. Participant Contact Information Form V1.1 07Jan2026 TC]	1.1	07 January 2026
Referee's report or other scientific critique report [Peer review]		28 October 2025
Referee's report or other scientific critique report [Peer Review]		23 October 2025
Research protocol or project proposal [Protocol]	V1.1 TC	07 January 2026
Summary CV for Chief Investigator (CI) [CI CV]		26 October 2025

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.

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: Quality assurance - Health Research Authority (hra.nhs.uk)

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: Learning - Health Research Authority (hra.nhs.uk)

IRAS project ID: 358225 Please quote this number on all correspondence

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

Yours sincerely

pp.

Dr Katie Meadmore
Alternate Vice Chair

Email:hampshirea.rec@hra.nhs.uk

Enclosures: **After ethical review guidance for sponsors and investigators – Non CTIMP Standard Conditions of Approval]**

Copy to: Mrs Shahista Hussain, OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST