Participant Information Sheet for Young People aged 16+

Study title	CIP/CIM in children and young people, version 2
Principal Investigator	
Sponsor	Oxford University Hospitals NHS Foundation Trust

We would like to invite you to take part in our research study. Before you decide, it is important that you understand what the study is about and what it would involve for you. Please, take time to read this information and discuss it with others if you wish. If there is anything that is not clear or if you would like more information, please, ask us.

1. What is the purpose of the research study?

You have been chosen to take part in this study because your doctors have diagnosed you with probable or definite critical illness polyneuropathy and/ or critical illness myopathy (CIP/CIM) during your stay in the paediatric intensive care unit.

Critical illness polyneuropathy and/ or critical illness myopathy (CIP/CIM) are very rare conditions where people admitted to intensive care due to a severe illness then develop weakness in their limbs, and sometimes breathing muscles, after the initial illness has improved.

There is currently only limited information on how children and young adults are affected by CIP/CIM. In this study we are aiming to identify as many cases as possible in the UK over an 8-year period including the last 5 years as well as the next 3 years (up to 2028). We want to look at the clinical features and long-term health outcomes in children and young adults with CIP/CIM.

2. Do I have to take part?

No, participation in this study is completely voluntary. It is up to you whether or not you take part. You may refuse to participate or withdraw from the study at any time, this will not affect your clinical care in anyway. If you do decide to participate you will need to read this information sheet and sign a consent form to show you have agreed to take part.

3. What will happen to me if I decide to take part?

If you agree to participate in the study, we (the study team at Oxford University Hospitals NHS Foundation Trust) will ask your local doctors to send us information that they have recorded about you. This will include all the information about your diagnosis and hospital stay including all the tests performed and medications given until your discharge from hospital.

We would also like follow up information about how you are walking (Hughes scoring) for 2 years after your discharge from the intensive care unit (ICU). If you were discharged more than 2 years ago, we will ask the hospital to send us this information if they collected it. If you were discharged more recently than this or are still in hospital, we will arrange video calls with you at 6, 12, 18 and 24 months following your discharge from the ICU. During this call we will ask you about your walking and ask you to show us how you walk. These calls will take no more than 30 minutes and we will schedule these at a time that is convenient for you. Your parents can join these calls if you would like. If you are still in hospitals for any of these timepoints we will ask your local team to carry out the assessment.

In order to carry out the follow up calls we will ask your local hospital to complete a participant contact information form which will include your; year of birth, NHS number, participant name, parent/ representative name (if applicable), an email address and phone number, which will be shared with the central study team. If there are any medical concerns raised in any of the follow up calls, the study team will inform your local clinician who will follow this up with you.

The study will not have any other tests or procedures.

4. What are the possible benefits of taking part?

There is no direct benefit to you from participating in this study. We hope that information gathered from this study may help doctors take care of children and young adults with CIP/CIM better in the future. There is no payment for taking part in this study.

5. Will my taking part in the study be kept confidential?

Yes, you will be assigned a unique study ID number that will be used to identify all study data. Information that can identify you will be kept separately from the study data. We will only use your name, date of birth, NHS numbers where this is necessary to link to your NHS records for data collection and contact you for remote consent or follow up video calls. Information that can identify you will only be held securely by the study team at Oxford University Hospitals NHS Foundation Trust (the study sponsor) for the purposes of the study. We handle information that can identify a patient very seriously and ensure it is kept safe and secure. We only collect the least amount of data that we need.

Responsible members of the Oxford University Hospitals NHS Foundation Trust, regulatory authorities <and the relevant NHS Trust(s)> may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

6. What will happen to my data?

The local doctors will send information to the research team via secure email. All the information will be safely stored on secure servers at Oxford University Hospitals NHS Foundation Trust where only the research team will be able to access it.

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The Oxford University Hospitals NHS Foundation Trust is the sponsor for this study. It is the data controller, and is responsible for looking after your information and using it properly.

We will be using information you provide and from your hospital records in order to undertake this study and will use the minimum personally-identifiable information possible.

We will store any research documents with personal information, such as consent forms and participant contact information forms, securely at the Oxford University Hospitals NHS Foundation Trust for 3 years after the youngest participant reaches 18 years old or for 5 years, whichever is longer, after the end of the study, as part of the research record.

The local study team will use your name, NHS number, home address, and contact details, to identify your medical records and contact you about the research study. A copy of the consent form from this study will be kept in your medical records for as long as those records are retained. They will keep any other identifiable information about you from this study for 12 months after the study has finished to contact you about the study results.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Additional information can be found on the OUH website: https://www.ouh.nhs.uk/privacy/legal.aspx.

If you have further questions regarding how your data is used, and what choices you have about its use, then please ask a member of the research team in person or contact the principal investigator on the details listed at the end of this information sheet.

7. What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time without giving a reason. This will not impact your clinical care in any way. We will retain the data collected up to the point of withdrawal but no further data will be collected and you will not be asked to have any further follow up calls. If you would like to withdraw please contact the study team using the contact details at the end of this information sheet.

8. What happens at the end of the study?

After the study is completed, the research team will be publishing the information collected on the clinical features and outcomes identified in this cohort of children from across the UK. You will not be identified from any report or publication placed in the public domain. Findings can also be presented at conferences or shared with other researchers in a form that does not identify you. Once the paper is completed the research team will create a short summary for those who have consented to data being included in the publication which we would be happy to send through to you via email.

9. What if there is a problem?

If you have a concern about any aspect of this study, please speak with the Chief Investigator in Oxford, Dr Sithara Ramdas: sithara.ramdas@ouh.nhs.uk or her team at childrensresearch@ouh.nhs.uk, 01865 234332. They will do their best to answer your questions.

There are no special compensation arrangements. Oxford University Hospitals NHS Foundation Trust will provide indemnity for this study. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it.

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

You can speak to the Patient Advisory Liaison Service (PALS) which is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team please contact <INSERT RELEVANT NHS SITE PHONE NUMBER AND EMAIL FROM THE PALS WEBSITE>.

10. Who is organizing and funding the study?

Oxford University Hospitals NHS Foundations Trust is the study sponsor responsible for organising and conducting this study. This project has been funded by the Norman Collisson Foundation.

11. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by <INSERT REC NAME> Research Ethics Committee.

12. Further information and contact details

Please, contact Dr Sithara Ramdas (sithara.ramdas@ouh.nhs.uk) or her team childrensresearch@ouh.nhs.uk, 01865 234332 if you have any questions about the study.

You can also contact your local study team: <INSERT NAME> by <(telephone, e-mail, in writing)>

Thank you for considering taking part.