PARENT/LEGAL GUARDIAN INFORMATION SHEET

A study to understand how your child's body shape changes while having treatment for leukaemia

We would like your child to take part in our research study. Before you decide, you need to understand why the research is needed and what it would involve for you and your child.

Part 1 tells you the purpose of this study and what will happen to you and your child if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1 – information about the project

Leukaemia is a form of cancer that affects the bones. Our bones make important cells that fight off bugs that can enter our body through our lungs or gut. Therefore, if our bones are not working well this can increase our risk of infections. Drug treatment uses chemicals to kill leukaemia cells. Long-term survival rates for leukaemia treatment have increased due to advances in medication.

The type of medications used in the treatment of leukaemia can alter the amount of muscle and fat levels – this is called sarcopenia. These changes in your child's muscle and fat levels can reduce their overall energy (calories) requirements. This will be the first study to monitor changes in body shape and the impact this has on energy requirements in children undergoing treatment for leukaemia.

By understanding what changes are occurring to your child's body shape during treatment we hope to develop guidelines for healthcare professionals to help reduce these changes and therefore reduce the long-term problems related to a change in body shape (fragile bones and diabetes), which will also help the treatment work better and reduce the risk of having leukaemia again (relapse).

Why have we been chosen to take part? We are inviting all children and young people who have been diagnosed with leukaemia at Great Ormond Street Hospital to take part in this study.

Do we have to take part? No, it is entirely up to you. If you agree to take part, we will then ask you to sign a consent form. Participation is voluntary and even if you agree to take part, you are free to stop at any time, without giving a reason.

What will happen to my child if I agree to take part? If you agree to take part, we will meet with you and your child before treatment starts. We will use different types of scans that give

the researchers information about how much bone and muscle your child has. We will repeat these same measures throughout the treatment to see if there are any changes.

Radiation risk statement

If you decide your child can take part in this study, they will have a DEXA scan at the start and end of treatment. A DEXA is a type of X-ray that measures the structures within the bone. This can take up to 20 minutes. This will be an additional test that children with ALL would have if they did not take part in the trial. These procedures use ionising radiation to form images of your body to provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to you as a consequence of taking part in this study are about [insert estimated risk] %

A DEXA scan is a type of X-ray that measures the structures within the bone. This can take up to 20mins

Bioelectrical-Impedance: measure muscle and fat level. It has 4 leads that are attached to your ankles and wrists and takes 10mins to collect information

Indirect Calorimetry measures energy requirements by placing a space hood over the head to measure breathing and takes 10 minutes to collect information

What will we have to do? Your child's treatment will follow the usual routine clinical practice for all children on the ward. The team will carry out the usual assessments for your child**.** We will also perform the additional nutritional status intervention as outlined above: including body composition measurements (DEXA scan), indirect calorimetry and diet history

What are the disadvantages of taking part? Medical treatment will be no different if you are not taking part.

5. COVID-19 Related Risks. Please be advised that if you have tested positive or have any symptoms of COVID-19 we will postpone any face-to-face activities until a later date.

We understand that you may feel worried or have anxiety around participating in face-to-face activities, other methods (online or remote) will be offered, where possible. All research activities will follow both Great Ormond Street, Government and University guidance. Please be mindful that face-to-face participant interactions still have a potentially increased risk of exposure to COVID-19 by attending face-to-face, despite the mitigating actions (wearing face mask/ hand washing) to reduce risk.

What are the possible benefits of taking part? There are no advantages at this early stage of the study but the results may provide insight and information to identify children who are at greater risk of developing sarcopenia during and after treatment and therefore ensure appropriate medical and dietetic intervention is accessed.

By monitoring and understanding when these changes occur throughout drug treatment, we hope to be able to reduce the development of sarcopenia, which will make the drugs work better and improve your child's recovery.

What are the side effects of the study? There are no perceived side effects of this study. All the body composition measurements are non-invasive and are not painful. Bone density (DEXA) scans are very safe. They use a much lower level of radiation than standard X-rays,

which means that the radiographer (the technical specialist carrying out the scan) can stay in the scanning room with you during the scan

What happens when the research stops? We will collect all the information from all the children, and we will perform analysis to help understand this complex syndrome.

What if there is a problem? Any complaint about the way you or your child has been dealt with during the study or any possible harm you or your child might suffer will be addressed. Detailed information on this is given in **Part 2**.

Will my child's taking part in the research be kept confidential? Yes. We will follow ethical and legal practice and all information about your child will be handled in confidence. The details are included in **Part 2**.

Who will have access to my child's medical/research records? Only the researchers involved in this study will have access to your child's medical records and data collected during this study. The Sponsor and Regulatory Authorities may require access to such data and medical records to monitor and audit the conduct of the study.

We will tell colleagues around the world what we have learned in the study in reports and publications, but nobody will learn anything personal about your child, or any other child by reading these reports or publications. Your name or your child's name will not appear in any reports or publications. We are following the government's strict rules about how information like this must be stored to keep it secure. We may need to keep the research data for up to 20 years.

Information and data generated from this study may be used to aid future research which will impose the same strict confidentiality process as this study. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it. We will make sure no one can work out who you are from the reports we write.

Who should I contact with any questions?

Thank you for your time and for considering taking part in the study. If you decide to take part, you will be given a signed consent form to keep. If you require further information with regards to the study, please contact:

Contact for further information
Principle Investigator
Dr Graeme O'Connor 0207 4059200 **ext** 5840

Sponsor Organisation*:*

Joint Research and Development Office (R&D*)*

Great Ormond Street Hospital NHS Foundation Hospital

Great Ormond Street

London, WC1N 3JH

Research.Governance@gosh.nhs.uk (please do not send sensitive or personal data)

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2 - more detail – information you need to know if you still want to take part.

What if new information becomes available?

It is possible that we might get information through more in-depth discussions with you, and this may alter the treatment your child may benefit from. This is not likely, but if the situation does arise, we would like permission to discuss this with your clinical team. If this happens, someone from the research team will tell you and your child about it and discuss it with you. This will not affect your child's place in the study, but if you do choose to withdraw at any time this will not affect any care your child receives whilst in hospital. If you decide to continue in the study, you and your child will be asked to sign an updated consent/assent form.

What if there is a problem/Complaint?
If you have a concern about any aspect of this study, you should speak to the research team who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this through the normal hospital complaints procedure and contact the following person:

Chief Investigator Dr Graeme O'Connor 0207 4059200 ext 5840

Patient Advice & Liaison Manager
Mr Luke Murphy
Great Ormond Street Children's NHS Foundation Trust
Tel: 02074059200 ext 7862
Luke.Murphy@gosh.nhs.uk **or** pals@gosh.nhs.uk

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

at: www.hra.nhs.uk/information-about-patients/

or: Sponsor's Data Protection Officer email: Your.Data@gosh.nhs.uk

or: Great Ormond Street Hospital Privacy Notice: https://www.gosh.nhs.uk/privacy/

or: by asking one of the Research Team

Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 2018 and the General Data Protection Regulations 2016 (GDPR).

Your child's medical notes may also be looked at by other people within the hospital involved in the running and supervision of the study to check that it is being carried out correctly.

Harm

In the unlikely event that something does go wrong, and your child is harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation – but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Will any extra laboratory or genetic tests be done?
No extra tests outside of those required by your hospital doctors, for clinical reasons, will be done. No genetic testing will be done.

1. What will happen to the results of the research study?
When the study has finished, we will present our findings to other doctors, and we will put the results in medical magazines and websites that doctors read. We would also like to put a summary on the hospital website so that you will be able to read about our results too. Results will also be presented at national and international conferences.

2. Who is organising and funding the research?

The study will be delivered as part of a research degree and will be funded by King Abdulaziz University

3. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given a favourable ethical opinion for conduct in the NHS by the Central London Ethics Committee.

Who should I contact with any questions?

Chief Investigator

Dr Graeme O'Connor

0207 4059200 ext 5840

If you and your child decide to take part in this study, you will be given this information sheet and signed consent and assent forms to keep.

Thank you for taking the time to read this information sheet.