Full Participant Information Sheet

HALO study: HAematology **L**ived experiences and **O**utcome

You are being invited to take part in a research study involving people who were diagnosed with Beta Thalassaemia, Acute Leukaemia or a Sickle Cell Disorder before the age of 18 years.

Before you decide whether to take part, please read this information sheet to find out why the research is being done and what it involves. Please ask the research team or your hospital team if you have any questions.

What is the purpose of the study?

This study aims to understand people's experience of their condition. This includes health care, educational and social outcomes, and the support received.

To do this, we will access routinely collected NHS information from national registries and additional educational attainment data. This data will be linked together to provide important and comprehensive information on peoples' journeys across multiple aspects of life.

To create a more complete picture of experiences, quality of life and outcomes, consenting participants will also be asked to complete a survey. This will be used to support improvements in care.

All personal identifiable information will be removed when we receive it for analysis and we will not be able to directly identify any individuals from the data.

Who is doing the study?

NHS Hospitals across the North of England and the University of Leeds are doing the study.

Professor Adam Glaser, Professor of Paediatric Oncology and Late Effects, University of Leeds (Honorary Consultant, Leeds Teaching Hospitals NHS Trust) and Professor Richard Feltbower, Professor of Paediatric Epidemiology at the University of Leeds are the Lead Investigators. They lead the study and have overall responsibility for it.

The study is co-ordinated by an experienced group of researchers with medical, scientific and patient backgrounds. It includes a local patient and public involvement and engagement group, and a clinical advisory group.

The University of Leeds is the study sponsor and Leeds Hospitals Charity have funded the study.

Why are you being invited to take part?

You are being invited to join this study as you received a diagnosis of beta thalassaemia before the age of 18 years.

Before you decide whether to take part or not, it is important to understand why we are asking for your participation and what it involves. If you have questions or need more information, please feel free to contact the HALO research team, details can be found at the end of this information sheet.

Am I eligible to take part?

You can take part if you were diagnosed:

- with beta thalassaemia before the age of 18 years, and
- were diagnosed on or after 1st January 1990, and
- you are registered with a hospital that is part of the North East or North West England Haemoglobinopathies Co-ordinating Centres, and
- you are now at least 18 years old.

What will I be asked to do?

If you choose to take part, you will be asked to complete a survey either online, on paper or by phone. Language support is available if you take part by phone. The survey is managed by IQVIA, an established survey company approved by the NHS.

You will be asked to complete questions about your diagnosis, the impact of your condition on your health, work, education, and quality of life. You do not have to answer all the questions if you do not want to. You do not need to complete the survey in one go. You can take a break and come back to the questions later. If filling in the survey online, you will be able to log back in at any point and change your answers or continue until the point when the complete button on the final page is pressed.

What are the potential benefits of taking part?

Research delivers wide gains to society, so that others with a similar condition and experiences may benefit from improvements in care and support based on what we find from this research study.

What are the possible disadvantages and risks of taking part?

Whilst these are likely to be small, the questionnaires may present a challenge both in the time taken to complete it and be a possible reminder about significant past events in your health, educational and social experiences.

If this happens you can contact IQVIA using their Helpline 0800 7831775, where trained staff can help direct you to appropriate support.

Do I have to take part?

No. However, by taking part, you will be helping us understand the longer-term impacts of a childhood diagnosis of beta thalassaemia. Any decision about your participation will not affect the standard of care or treatment you receive.

How will we use information about you?

The information provided will be used to identify the experiences and longer-term outcomes of a childhood diagnosis of beta thalassaemia.

Your personal details have been used to identify you from routinely collected NHS sources and national registries. By completing the survey, you are consenting for your responses to be studied with those of other participants. This will include any free text or quotations. If free text or quotations contain any identifiable information, e.g. name or specific dates of events, this will be removed before the survey data is shared with the HALO research team.

To learn as much as possible, we would like to link your answers to routine data held about you by the NHS. You will be asked to agree to this at the beginning of the questionnaire, and you will be able to say no to this if you wish. If you do not want to link your survey responses to your existing NHS data, this will not affect the care you receive from the NHS.

We will need to use information from you, your medical records and routinely collected NHS data sources for this research project.

This information will include your:

- Name,
- NHS number,
- Date of birth,
- Postcode,
- Gender,
- Mobile number (if known).

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Leeds is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure.

Your personal information will be kept confidential. The University of Leeds, overseeing this study, is responsible for safeguarding your information. To protect your identity, all identifiable details that could show it is you will be removed by IQVIA. Only anonymised data will be shared with the research team.

Survey responses will be stored for 10 years after the survey closes for audit purposes and disposed of in a confidential manner after this period of time. If you would like to know more about what personal data will be accessed, please go to the HALO Study website: **https://halohaemstudy.org.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, but we will keep information about you that we already have.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

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

You can find out more about how we use your information

- our leaflet available from a member of your care team
- by asking one of the research team
- by sending an email to **HALO_study@leeds.ac.uk** or you can contact the University of Leeds Data Protection Officer via email: **dpo@leeds.ac.uk** or
- by ringing us on 0113 343 0499.

Data Protection and your Rights

In the UK we follow the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act (2018). All research using data belonging to an individual, must follow UK laws and regulations. Universities and the NHS use patient data in research to help towards improving health and care in the NHS. In legal terms this means that universities use patient data in research as part of 'a task in the public interest'. An NHS research ethics committee reviews and approves the study before the research starts. You will be asked if you agree/consent to take part in this research.

By taking part in the survey, you are giving us your consent to use your personal information in accordance with the study's objectives.

You can withdraw from the survey at any time prior to pressing the complete button on the online questionnaire, or returning the paper version, or completing the survey on the phone. After completing the questionnaire, you may be able to withdraw from the survey up to the point when the data is ready for analysis. If you would like more information about how to withdraw, please contact IQVIA by calling their Helpline 0800 7831775.

If you would like to withdraw from the data linkage part of the study, please contact the HALO team using the following email address: **HALO_study@leeds.ac.uk** or phone number: 0113 343 0499.

Option to decline participation in the data linkage part of the study

Even if you have agreed to participate in the survey, you will have an option not to be included in the data linkage part of the study.

For information on how you can opt-out of the data linkage, go to the HALO study website Opt-Out Policy: **https://halohaemstudy.org.uk/wp-content/uploads/sites/160/2025/05/336672_22_Opt-out-Policy_v1.0_20241007.pdf** or contact Professor Adam Glaser or Professor Richard Feltbower, Senior Researchers

- In writing to: Leeds Institute for Data Analytics (LIDA), Worsley Building, University of Leeds, Leeds LS2 9NL
- By email: **HALO_study@leeds.ac.uk**
- By phone: 0113 343 0499

The study has been approved by the NHS Health Research Authority (HRA) Confidentiality Advisory Group (CAG) (HRA/REC: 24/YH/0186; CAG: 24/CAG/0138).

Publication of Results

HALO results will be shared with people affected by haematological conditions and professionals involved with their routine health, education, and social care. Results will be published in academic journals and shared with NHS teams and policy makers. No patients will be identified in any report or publication.

What if there is a problem?

If you wish to make a complaint about the study you can contact the University of Leeds, sponsor office by email: **governance-ethics@leeds.ac.uk**

Alternatively, you may wish to contact your local hospital's Patient Advice and Liaison Service (PALS).

Contact details

If you have questions about any aspect of the HALO study, you can contact the team via email: **HALO_study@leeds.ac.uk** or phone: 0113 343 0499. We will reply as soon as possible.

Where can I get more information about the study?

The full HALO study protocol, information regarding the process of obtaining ethical approval and the HALO study Opt-Out Policy are all available by inserting the following weblink into your browser: **https://halohaemstudy.org.uk** or by scanning the QR code on the side of this section:

Prize draw

To thank you for your help in taking part in the survey, at the end of the questionnaire you will have the option to enter a free prize draw to win £100 of *Love2shop* vouchers.

How to take part

If you would like to take part in the study, please scan your unique QR code below and follow the instructions. To book completion of the survey on the phone (with a translator if needed) contact IQVIA on their Helpline (Freephone) number 0800 7831775.

Your unique QR code

To find out more about the survey see the HALO study web address: https://halohaemstudy.org.uk

To request a paper version or phone option, please call: IQVIA Helpline (freephone): 0800 7831775

To contact the HALO research team directly please use: HALO_study@leeds.ac.uk or 0113 343 0499