Scientific Advances in Infant Acute Lymphoblastic Leukaemia (SAIL) – Parent Information Sheet

Welcome!

- We would like to invite you and your child to take part in the SAIL Research Database. A Research Database is a digital collection of scientifically valuable data which helps facilitate future research in specific areas. The SAIL Database will facilitate future cancer research.
- Providing data to the database is entirely voluntary. Before you decide, it is important that you understand why the research is being done and what it would involve for you and your child.
- Please take time to read this information and discuss with others if you wish. If anything is not clear, or you would like more information, please contact us on: sail@medsci.ox.ac.uk
- You can take as much time as you need to think about participating. If you don't want to join, you don't have to, and this decision won't affect you or your child's healthcare or legal rights.
- You will not have to attend any additional hospital appointments and your child will not have to undergo additional medical tests (above those required for routine care) as a result of participation.
- By conducting cancer research, doctors and scientists hope to learn more about how cancer can be detected, diagnosed, treated and prevented. The ultimate aim is to improve patient care and overall quality of life by providing personalised treatment. Cancer research done today will help shape better medical practice in the future. We hope you will join us in this mission.

Why are we creating this database?

- Although it is possible to cure 9 out of 10 children with the commonest type of blood cancer (leukaemia), unfortunately there are some children with leukaemia who cannot be cured. A better understanding of these "high-risk leukaemias" is needed in order to cure every child with leukaemia.
- One type of high-risk leukaemia is infant acute lymphoblastic leukaemia (ALL) which occurs in babies less than a year old. With current treatments only around 50% of babies can be cured. Currently, there are no ongoing clinical trials in the UK investigating this condition, but since 2021, all infants with ALL are being treated on a UK National Cancer Research Institute

(NCRI) Leukaemia sub-group national guideline. These guidelines are designed to cause less side-effects and be more individually tailored for this vulnerable patient population.

- At the same time, new NHS laboratory tests are being performed at diagnosis and throughout follow-up of these patients, in order to better understand the disease and monitor individual responses to treatments. Similarly, scientists are also performing tests on samples from these infants to investigate which genes are behaving abnormally in the leukaemia cells, and whether these faulty genes can be targeted during treatment.
- The SAIL Database aims to bring together large amounts of data about infants affected by ALL from sources such as laboratory tests, clinical follow up data, research data and information gathered directly from parents. By combining these data sources, we hope to develop a large research resource to facilitate ongoing and future research into ALL.

For more information on infant acute lymphoblastic leukaemia, go to:
https://www.cancerresearchuk.org/about-cancer/childrens-cancer/acute-lymphoblastic-leukaemia

What is the aim of the database?

- The overall aim of SAIL is to establish a high-quality, interactive, national database in order to facilitate ongoing and future research into infant acute lymphoblastic leukaemia (iALL). In order to achieve this, SAIL will work towards the following three aims:

1. To gather data in order to create a national database aimed at offering valuable information about the best treatment methods of iALL.
2. To analyse each participant's leukaemia in detail, including specific biological markers, to gain a better understanding of the disease and how it responds to treatment.
3. To test if combining and studying various types of data from different sources can help create customised treatment plans for each participant.

Why have I been invited to take part?

- You and your child have been invited to participate as your child was diagnosed with ALL or mixed phenotype acute leukaemia (MPAL) when they were aged 365 days or less.
- As SAIL aims to create a resource that will facilitate future cancer research, the database will recruit participants over an initial five-year period. We plan to recruit up to 200 infants during this time.

Does my child have to take part?

- No, taking part is entirely voluntary. The medical care your child receives won't be affected in any way if you decide not to take part.
- If you do decide to take part, you can withdraw yourself and your child at any time if you change your mind. You won't have to give a reason. Should you decide to withdraw, you will not be asked to provide any further data about your child.
- Data will only ever be shared with researchers in a way that cannot identify you or your child, and can never be traced back to you (more information on data security is provided later in this Parent Information Sheet).

How do I join the database?

- If you're interested in taking part in the study, you must first give your informed consent to do so on behalf of you and your child, and only after you have read and fully understood the information in this Parent Information Sheet.
- Informed parental consent is confirmed electronically online (paper versions of the parent information sheet and consent form will be made available on request) via a secure web-portal called "REDCap" which is accessible via the Oxford Cancer website (www.cancer.ox.ac.uk/sail).
- As part of the consent process, we will ask you for some personal data relating to your child including biological sex, date of birth and NHS number, your personal data will be stored separately, and be available only to clinical research members of the team.
- You will also be asked if you would be happy to be approached by the University of Oxford regarding participation in future research studies. You do not need to consent to this in order to participate in SAIL.
- Once you have completed the registration process, you will receive a confirmation email containing a SAIL code, which is unique to you. Rather than using your personal data, this code will be used to identify you and your child throughout your participation. All your records, including data collected directly from you, will be saved using this code, never your personal data. The provision of this code makes all data related to you "pseudonymised."
- If you'd like assistance with completing the online consent form, just let your care team know. They will help you during your next appointment.

If I decide to join the database, what would participation involve for me and my child?

- A major part of SAIL is collecting data relating to infants with ALL directly from their parents, known as "parent reported outcomes". To do this, we will ask you to input data directly onto

the SAIL database. You will be sent a link to the SAIL database once your registration is confirmed. You can access the SAIL database by inputting your unique study code.

- The data we will ask you to input will be focused primarily on your child's response to treatment. We will formulate these questions in consultation with parents, so please indicate if you would like to be part of this consultation in the consent form. For example, we will ask you to enter details of:
    - any side-effects following treatments, including symptoms, how long the symptoms lasted and how your child recovered
    - any new symptoms which you do not think are related to treatment
    - any changes in feeding habits
    - any changes in sleeping patterns
    - any other changes in behaviour
- We may send you email reminders to complete data entry on the SAIL database. For example, we may email you monthly to ask if anything has changed with regard to your child's response to treatment and overall health.
- Remember, inputting data is entirely voluntary, and you can opt-out of receiving these reminders. You do not have to share any information you do not want to share.
- Your participation in SAIL is finished 24 months following the date your registration was confirmed. We will not ask you to input any more data after this date. However, we may still contact you in order to invite you to parent network events, share overall progress of the database or invite you to share your feedback. You can always opt-out of receiving any communication from the SAIL team by emailing: sail@medsci.ox.ac.uk.
- We understand that participating in cancer research may sometimes be distressing. If you ever feel like you need support, please consider speaking to your child's cancer care team, or viewing support services available on www. bloodcancer.org.uk.

Will you access my child's medical records?

- With your consent, members of the SAIL team will access medical data relating to your child held on pre-existing sources, such as NHS databases and cancer registries. Only individuals who have appropriate permissions from the NHS will be able to access these data.
- By accessing these resources, the SAIL team can obtain detailed and scientifically valuable data such as diagnosis information, treatments received and any medications administered.
- Data obtained from these resources will be combined with data provided directly from you on the SAIL database, greatly enriching the resource. Any data obtained from external sources and linked with the SAIL database will only be referred to by your unique code.

Will you take any samples from my child during the study?

- No, we do not ask for any additional samples from your child.
- It is highly likely that samples have already been obtained from your child as part of their routine care. Sometimes, doctors and scientists may use these samples for research purposes (only with your consent). During the SAIL consent process, we will ask your permission to obtain any data generated through research (known as "research data"), which has already been conducted on your child's samples and which you have already consented to, in order to further enrich the SAIL Database.

What should I consider?

- As participation in the database requires no additional hospital visits or medical procedures, you do not need to change anything regarding your child's medical care in order to take part.
- Providing details on your child's health may sometimes be stressful. Remember, providing this data is entirely voluntary, and you do not need to share anything you do not want to.

Are there any risks of taking part?

- Overall, participation in this study is considered very low risk, as SAIL requires no additional hospital visits or medical procedures.

What are the possible benefits of taking part?

- You and your child will not directly benefit from taking part. However, the information we gather from database participants might benefit other infants with ALL in the future.

Will taking part in the database be confidential?

- Yes. When you register and agree to participate, our database will generate a study code that is unique to you. All of your study records, including any data provided, will only be identifiable by this study code.
- We will only use your child's name, date of birth, biological sex and NHS number when this is necessary to link NHS records with this study, for example, checking to see the status of your child's cancer and accessing medical records to look for relevant diagnostic tests. We ask for this identifiable data as more than one data-type is required to ensure the correct medical records are accessed.
- Information that could identify you or your child will only be held securely on trusted research servers monitored directly by the SAIL team. Identifiable information relating to you

or your child will only ever be used for the purposes of the SAIL database and will never be shared.

- Responsible members of the University of Oxford, regulatory bodies or NHS Trusts involved in the database may be given access to personal data for monitoring and/or audit of the database to ensure that the research is complying with applicable regulations.

What will happen to my data?

- 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 University of Oxford is the data controller, and is responsible for looking after your information, keeping it secure and using it properly.

- We will be using information provided by you, your child's hospital, NHS England and any other NHS registries in order to undertake this research, and will use the minimum personally-identifiable information possible.

- In the future, data relating to your child and collected from you may be shared with academic, NHS and commercially-led researchers, in the UK and abroad, in order to be used in future cancer and/or other appropriate research. All external data requests will be assessed and approved/rejected by a data access committee. It will not be possible to identify you or your child from any data provided or collected, **and no identifiable data will ever be shared with researchers**. All data you provide will be labelled using your SAIL study code and never your personal information, this is known as pseudonymisation.

- We will only share your pseudonymised data with researchers if you have provided your consent for us to do so. Your data will only ever be shared in a manner that cannot identify you. In the future, your data may be shared with researchers based outside of the EU. We are required to inform you that such countries might not offer the same level of protection of privacy as that demanded by law in the UK.

- We will store any research documents with personal information, such as electronic consent forms and your contact details, securely at the University of Oxford for a maximum of 5 years after recruitment to the database has finished, as part of the research record. We will keep identifiable information about you and your child for 5 years after the database has finished.

- If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form securely until such time as your details are removed from our database. We will keep the consent form and your details separate from one another and any research data

- 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. Further

information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

How have parents and the public been involved in the database?

- Parents who have relevant lived experience of infant/childhood ALL, and other volunteers with relevant lived experience of cancer, were consulted on the design of the database, including what data should be collected, and were questioned on whether parents thought there was a need to undertake this research at all.
- Additionally, parents were asked to advise on certain practical aspects of taking part (for example, if using an online consent is a good idea). These individuals were also asked to review the consent form, this parent information sheet and any other "parent-facing documents."
- Crucially, parents are to be consulted on the design of the parental reported outcome questions, by providing feedback on what information related to their child they feel would be most important to collect.
- Parents with relevant lived experience of infant ALL will continue to be informed on SAIL progress, and be provided the opportunity to give feedback through workshops, including on how best to present results to participants and the wider public.
- Any changes to parent facing documents will be reviewed and approved by parent representatives before they are finalised and used.

Will I be informed of research results?

- Lay summaries of key results arising from research using data from the SAIL Database will be shared on the SAIL webpage, or communicated to participants via newsletters.

Who is organising and funding the database?

- The Chief Investigator responsible for leading SAIL is Prof. Anindita Roy, Professor of Paediatric Haematology. Prof. Roy is based at the University of Oxford, and also works as an honorary consultant at Great Ormond Street Hospital, London.
- The study is managed by the University of Oxford CRUK Centre and the University of Oxford. This means they are legally responsible for database organisation and for overseeing the work of the researchers.
- The database is funded by a grant awarded by Cancer Research UK.

What if there's a problem?

- If you have a concern about any aspect of SAIL, please speak with the SAIL team via email: sail@medsci.ox.ac.uk. They will do their best to answer your questions.
- The investigators recognise the important contribution that volunteers make to medical research, and will make every effort to ensure your safety and wellbeing. The University of Oxford has appropriate insurance in place in the unlikely event that you or your child suffer any harm as a direct consequence of you or your child taking part in this research. If something does go wrong, you or your child are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the University will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary. If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this research, contact the SAIL team via email or you may contact University of Oxford Research Governance, Ethics & Assurance (RGEA) at rega.complaints@admin.ox.ac.uk or on 01865 616480.
- The Patient Advisory Liaison Service (PALS) 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. If you wish to contact the PALS team, please email complaints@ouh.nhs.uk or call 01865 221473.

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. SAIL has been reviewed and given a favourable opinion by East Midlands – Derby Research Ethics Committee.

Participation in future research:

- During the consent process, we will ask your permission to contact you about opportunities to participate in future research being conducted by the University of Oxford. Your decision about this will not affect your ability to participate in SAIL.
- All contact regarding future research opportunities will come from the SAIL research team in the first instance. Agreeing to be contacted does not oblige you to take part in future research, and you can ask to be removed from the register at any time without providing a reason.
- Your contact details will be held securely, separately from this database on a password protected computer in the Department of Oncology accessible only by authorised individuals.

Further Information and Contact Details

If you should have any questions, please contact the SAIL team on sail@medsci.ox.ac.uk.

Thank you for reading this information.

I confirm I have read and understood all of the information in this patient information sheet and are happy to begin the consent stage. [TICK BOX]