Patient notification and Privacy notice for project: Leukaemia in Pregnancy registry study (LIPS).

I have questions or want further information. Who do I talk to?

If you have any questions or concerns about how your data will be processed within this project please contact Hull Health Trials Unit (HHTU) in the first instance:

Email: hhtuenquiries@hyms.ac.uk Telephone: 01482 463444

Address: 3rd Floor, Allam Medical Building, University of Hull, Hull, HU6 7RX

If you would like further information, please contact the University of Hull, Data Protection Officer (DPO):

Email: dataprotection@hull.ac.uk Telephone: 01482 466594

Address: University of Hull, Cottingham Road, Hull HU6 7RX

What is this project about?

Acute leukaemias (AL) are aggressive blood cancers that can affect people of any age, including women who have AL during pregnancy or who may want to bear children in the future. For women who are pregnant when they have AL, medical professionals are faced with a difficult balancing act: to treat the cancer effectively without harming the foetus.

British guidelines recommend that women are treated without delay, but this should be balanced against the risks of chemotherapy to mother and baby as determined by stage of pregnancy and multi-disciplinary team review (Ali et al 2015). Although of great value, these guidelines are mainly based on either low-grade evidence or the opinions of experts in the field.

The aim of the LIPS study is to understand more about the treatment and outcomes of patients diagnosed with AL during or prior to pregnancy. This study will establish a research database of Leukaemia in Pregnancy, initially collecting data from cases since August 2009, and any new cases that are diagnosed, from centres all across the UK. Subject to further funding being secured, the database will be continued beyond the initial funding period.

The data will be used to create clear evidence based recommendations for how to treat and manage AL in pregnant women and those who might later want to become pregnant. These future recommendations will help to offer both the parent and baby the best possible care and chances of survival.

What data are you using?

In the Leukaemia in Pregnancy study (LIPS) we are collecting data on the following cases:

Current cases:

1. Where patients are currently receiving treatment **whilst** pregnant
   Or
2. Where patients have previously received treatment and are **now** pregnant.

Historical cases requiring consent:

1. Where patients had treatment for AL during pregnancy and are still in active follow up and/or are in contact with the clinical care team.
   Or
2. Where patients had a previous AL diagnosis and subsequently became pregnant after treatment, and are still in active follow up and/or are in contact with the clinical care team.

Historical cases processed without consent:

In historical cases where the patient had treatment during pregnancy or subsequently became pregnant after treatment, but…

a) …are no longer in active clinical follow up. This may include: Discharged – either following treatment completion or as a result of not attending clinic appointments
b) …are no longer in contact with the clinical care team
c) …are known to have died

The data will be processed without consent subject to the relevant approvals being given. For further details see the section on '**Accessing your data without consent'**.

Hospitals will routinely collect data as part of your clinical care records. The LIPS database will contain information on treatment choices, outcomes and side effects for the parent and the child, in people who are pregnant at the time of AL treatment or become pregnant following treatment for AL after August 2009.

Am I in this dataset?

If you were pregnant after August 2009 and had AL at the time or had previously been treated for AL you may have been added to the LIPS database. If you are classed as a current case, or are a historical case but still are in active routine follow-up with the treating centre, you will have been asked for your consent before being added to the LIPS database.

If you think you could be classed as a historical case but are no longer in active follow-up with the cancer centre, you may have been added to the LIPS database without your consent. To have access to your data the HHTU have followed a formal process. For further details see the section below.

Accessing your data without consent

For certain historical cases where the patient is no longer in active follow-up with the hospital, HHTU have applied for permission to access data without consent. Decisions on the appropriateness of this are made by the Confidentiality Advisory Group (CAG) in England and Wales. They are an independent group who advise the Health Research Authority. Similar groups exist for Scotland and Northern Ireland who will also be applied to. The rationale for this approach is:

- Contacting a patient no longer in follow-up or regular contact with the care could cause unnecessary emotional distress to them or their families.
- Due to rare nature of the study population, the database needs to contain as high a percentage of cases as possible.
- Minimum identifiable information is being collected – the HHTU cannot identify you from the data captured.

More information about the Confidentiality Advisory Group (England and Wales) including a register of all data released under this process is available here.

More information about the Public Benefit and Privacy Panel for Health (Scotland) is available here.

The LIPS database does not collect any directly personal identifiable details (e.g patient name, date of birth or address) therefore the HHTU research team are unable to identify individuals in the database. Despite this, due the rarity of the population, we are treating it as identifiable as although very unlikely, when in viewed in combination with other external data sources in theory it could become identifiable.

The cancer centre where you received your treatment for AL are responsible for collecting your data and will know if you have been included. If the cancer centre is based in England they should have made checks of the national opt-out repository (https://digital.nhs.uk/services/national-data-opt-out-programme) for any previous dissent to the use of your data in research you may have made. This does not apply for Scotland, Wales and Northern Ireland. If you would like to confirm you have not been included, in the first instance, please contact the cancer centre where you had treatment to confirm whether you have been included or not.

If you have previously opted out of your data being used for research purposes but have been included in error without your consent or wish to remove your consent,

the HHTU research team will work with the specific cancer centre to meet any request or objection you might have, using your rights under GDPR 2018 as described below.

How will you look after the data?

Your data will be managed and stored by the Hull Health Trials Unit (HHTU) using their data capture system REDCap cloud and BOX Governance file storage system. Both systems have were assessed as part of a comprehensive procurement process. If you provide consent electronically, this information will have been collected using DocuSign. The HHTU hold a Data Security and Protection Toolkit (DSP) which provides assurance that they are practising good data security and that personal data is handled correctly. More information about the DSP can be found here.

How long will you keep it?

As a database, subject to funding, the dataset will continue beyond the initial funding period. The University of Hull will keep identifiable information about you by retaining the consent forms until 5 years after closure of the research database in Box. No directly identifiable data is included in the data collection database. However, as an additional precaution taken to protect patient identification, once all information has been collected (all data up to 4 years post-delivery) all data collection event dates will be randomly changed making your data anonymous. This will be performed at the end of the initial study period (mid to late 2021) and on a yearly basis from then on for the duration of the database. This anonymised data will be entered into the long-term database and the original data deleted from the data collection database. Once the data is in long-term database it will be anonymous. There will be no way of identifying individual patient data from this point onwards and no way to delete it.

What is the purpose of the General Data Protection Regulations (GDPR 2018)?

Under the GDPR 2018, there is a legal basis for processing personal data we collect about you during research as this is being done in the public interest (schedule 6) and for scientific research purposes (schedule 9).

The University of Hull is the data controller of the information it collects and processes as described in this Notice. This means that it has the core legal responsibility to safeguard the information and ensure it is processed lawfully. The law is set out in the EU General Data Protection Regulation (called “GDPR”) and a new UK law, the Data Protection Act 2018. In particular UOH must:

- Take steps to ensure that the data it processes is accurate and up to date;
- Give you clear information about its processing of your data, in one or more privacy notices like this one and the participant information sheet (referred to together in this section as a “Privacy Notice”);
- Only process your data for specific purposes described to you in a Privacy Notice, and only share your data with third parties as provided for in a Privacy Notice; and
- Keep your data secure.

The law states that we can only process your personal data if the processing meets one of the conditions of processing in Article 6 GDPR. As we are processing your special category data we also must meet one of the conditions in Article 9 GDPR. Special Category data includes personal data which relates to your ethnicity, sex life or sexual orientation, health or disability, biometric or genetic data, religious or philosophical beliefs, political opinions or trade union membership. Under the data protection legislation we need to explain the legal basis for holding your data, i.e. which of these conditions apply.

For our research project the following conditions apply:

• Article 6.1(e) of the GDPR, i.e. our processing is necessary for the performance of a task carried out in the public interest. Research is a task that UoH performs in the public interest, as part of our core function as a university;

• Article 9.2(j) of the GDPR, i.e. our processing is necessary for research purposes or statistical purposes. This condition applies as long as we are applying appropriate protections to keep your data secure and safeguard your interests.

Your rights as a data subject

Under the data protection laws you have a number of rights in relation to the processing of your data. These are limited by the lawful basis under which we hold your data. Your rights are:

- Right to request access to your data as processed by UoH and information about that processing
- Right to rectify any inaccuracies in your data
- Right to place restrictions on our processing of your data

Please note that we are unable to identify you ourselves within the data we hold. As such we would need to work with the reporting site to identify if you are in any of the datasets.

If you would like to exercise any of your rights as outlined above, you can contact the DPO as above or visit the Data Protection page on our website: Available here.

We will always aim to respond clearly and fully to any concerns you have about our processing and requests to exercise the rights set out above. However, as a data subject, if you have concerns about our data processing or consider that we have failed to comply with the data protection legislation, then you have the right to lodge a complaint with the data protection regulator, the Information Commissioner:

Online reporting: https://ico.org.uk/concerns/ Email: casework@ico.org.uk
Tel: 0303 123 1113

Post: Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF