# ITHACA

Immunology of THymectomy And
Childhood CArdiac Transplant

## Participant Information Leaflet for young people 11 – 15 years

We would like to invite you to take part in our research study. Before you decide, it is important that you understand *why* the research is being done and *what* it would involve for you.

This leaflet is divided into two parts. **Part 1** tells you the purpose of this study and what will happen to you if you take part. **Part 2** gives you more details about how the study will run.

Please **take time** to read this information carefully. You can talk about it with your family and/or friends if you want.

**Ask us** if there is anything you don't understand, or if you have any questions.

**Thank you for reading this!**

## PART 1 – To give you first thoughts about the study

After an organ transplant, children and young people have a weaker immune system. This causes a small risk of developing a condition called posttransplant lymphoproliferative disease (PTLD). PTLD occurs when a group of white blood cells called 'B cells' grow out of control and transform (change) into harmful cells that can make you feel poorly. Most of the time, this is because of an infection of 'B cells' by a very common virus called Epstein-Barr Virus (EBV) which can also cause glandular fever.

Most people with transplants **DO NOT** develop PTLD, but the risk is slightly higher after a heart transplant compared to most other organs. We still do not understand the reason for this. We think there might be some differences in how well the immune system of children and young people with heart transplants works compared to people with other organ transplants.

We want to measure the number and function of different immune cells circulating in the blood just before transplant and at regular periods after transplant. We will also look at how well the immune system is able to produce immune cells to fight an EBV infection. This will help us to better understand how the immune system recovers after transplant and identify immune patterns that either protect people from developing PTLD or increase their chances of getting the disease.

## Why have I been asked to take part?

We are asking patients under 18 years old from around the UK, who like you, have been put on the transplant waiting list. We plan to involve 40 children and young people in this study.

## Do I have to take part?

No! It is entirely up to you. If you do decide to take part:

- We will first ask you if you'd like to sign a form to say that you agree to a blood sample being taken and stored before your transplant (a "screening" assent form). Your parents/carers will also be asked to sign a similar form (a "screening" consent form).

- When you are called for your organ transplant, we will confirm if you are happy to remain a part of the study. We will ask you if you'd like to sign a second form to say that you are happy to continue taking part in the study (an assent form).
-We will not include you in the study or use your blood sample unless you agree to take part.

- You will be given this information sheet and a copy of your signed assent form to keep. You are free to stop taking part at any time during the study without giving a reason. If you decide to stop, this will not affect the care you receive.

## What will happen to me if I take part?

We would like to take no more than an extra 3 teaspoons of blood during your usual blood tests. This will happen during routine appointments with your local transplant team and **will not usually** need additional hospital visits or extra needles. The first blood samples will be taken as close to the day of your transplant as possible. We would like to have talked to you about the study before taking your first blood samples. This may not be possible if your transplant team thinks there isn't a good time to do so before your operation. If this happens, any blood samples we take will be stored and not used until you have agreed to be a part of the study. If you decide not to take part, then we will destroy your blood samples as soon as possible. If you do decide to take part, further samples will be taken during your regular follow up clinic visits at 3, 6, 12 and 24 months after your transplant.

At the beginning of the study, we will collect information on your medical care from the transplant team. We will continue to keep in touch with the transplant team about your health and how you are getting on after each of your regular clinic visits for up to 2 years after your transplant.

## Is there anything else to be worried about if I take part?

Since the blood samples will be taken during your regular transplant tests, there will be no additional pain or discomfort from taking part in this research study.

Blood tests can be uncomfortable, but we have numbing cream or cold spray, so it doesn't hurt as much.

## Will taking part in the study help me?

No, but the information we get might help us understand how PTLD develops. This can help us discover ways to prevent people in the future from getting PTLD and/or develop new and better treatments for it.

## Contact for further information

If you would like any further information about this study, or if you are interested in taking part, you could contact:

| | |
|---|---|
| **Name**: Dr Simon Bomken | **Name**: Dr Ugo Offor |
| **Designation:** Consultant Paediatrician | **Designation:** Paediatric Registrar |
| **Department:** The Sir James Spence Institute, Royal Victoria Infirmary, Queen Victoria Road, Newcastle upon Tyne, NE1 4LP. | **Department:** The Sir James Spence Institute Royal Victoria Infirmary, Queen Victoria Road, Newcastle upon Tyne, NE1 4LP. |
| **Tel:** +44 (0) 191-282-4068 | **Tel:** +44 (0) 191-233-6161 |
| **Study email:** nuth.ithaca@nhs.net | |

**Thank you for reading so far – if you are still interested, please continue to read the additional information in Part 2 before making any decision.**

## PART 2 – More detailed information about the study if you still want to take part

### What will happen to the samples I give you?

We will run extra tests on your blood samples at NHS laboratories, Newcastle University research laboratories and other partnering laboratories in the country.

With your permission, any of your leftover blood samples can be stored safely within the Newcastle University biobank. This can be used for other approved research in the future. This is entirely your choice. Your involvement in this study will not be affected by your decision whether to allow us store and use your leftover samples in the future. If you ask at any time, your remaining blood samples will be destroyed.

### Who will know that I am taking part in the study?

We will keep your information confidential. This means we will only tell people who have a need or right to know. If you and your parents agree, we will write to your family doctor/GP to tell them that you have decided to take part in the study. The letter will explain what the study is about but will not include any information about your blood test results.

### What will happen to the information you collect about me?

Any information you give us will be kept completely private. We will only use a research code number to identify you. All personal details that could identify you will be kept safe and secure on password protected NHS computers. We will keep identifiable information about you such as contact details and assent forms for no more than 5 years after the study has finished.

### What will happen to the results of the study?

The results of the study will be published in medical papers which can be found on the internet and may also be presented at national/international conferences. We will make sure to remove any personal information that could identify you before the research results are published.

## Who is organising and paying for the study?

The study is organised by The Newcastle upon Tyne Hospitals NHS Foundation Trust. It is paid for by Cancer Research UK and The Lymphoma Research Trust. None of the researcher doctors are paid for including you in the study.

## Who has checked and approved this study?

Before any research in the NHS goes ahead, it has to be checked by a group of people called a Research Ethics Committee. They make sure that the research study is safe and that you are being treated properly. This study has been checked and approved by North of Scotland (2) Research Ethics Committee.

## What if I don't want to do the study anymore?

Just tell your parents and the research doctors that you don't want to take part anymore. You don't have to give any reason why. It is **YOUR CHOICE**.

## What should I do if I have a problem with this study?

If you have any concerns about this study, you should ask to speak to the researcher doctors or ask your parent/carer to talk to them and they will do their best to answer your questions. If you are still unhappy after this, you or your parent/carer can speak to the hospital's complaint team:

You can contact the Patient Advise and Liaison Service (PALS). This service is confidential and can be contacted on freephone: 0800 032 0202.

If you would prefer to make a formal complaint you can contact the Patient Relations Department through any of the details below:
Telephone: 0191 233 1382 or 0191 233 1454
Email: patient.relations@nuth.nhs.uk
Address: Patient Relations Department, The Newcastle upon Tyne Hospitals
NHS Foundation Trust, The Freeman hospital, Newcastle upon Tyne,

NE 7 7DN

**THANK YOU** for taking the time to read this leaflet!