

Please affix Patient label

**A Research Study into the Genetic Causes of  
PSC and childhood autoimmune liver disease  
INFORMATION LEAFLET FOR  
YOUNG PEOPLE AGED 11-15  
Version 1, 08.03.18**

We would like to invite you to take part in our research.

Our research started for adults with PSC (Primary Sclerosing Cholangitis) only, but now includes children. In children and young people there are different types of autoimmune liver disease, and the type of autoimmune liver disease can also sometimes change over time.

We now collect samples from children living with one of the following illnesses, as named by their doctors:

- Primary Sclerosing Cholangitis
- Autoimmune Sclerosing Cholangitis
- Autoimmune Hepatitis with possible biliary disease
- Autoimmune Hepatitis with no biliary disease yet

Before you decide if you would like to join, please read this information leaflet. It explains why we are asking for your help and what this will involve. We ask that you discuss this with your parents, carer, other family members or friends.

If you have any questions, please ask your doctor or nurse. Thank you.

**Why are we doing this research?**

This study is about working out why some young people, like you, develop the liver illness Primary Sclerosing Cholangitis (PSC) or related autoimmune liver diseases. Scientists, doctors and nurses are working with people with PSC and related autoimmune liver diseases, to understand why they get these problems. They want to learn more about our genes and how our bodies work.

Genes are the building blocks that determine things such as the colour of our hair, eyes and even the shape of our bodies. They also play an important role in keeping us

healthy. The more we understand about these genes the more chance we have of preventing and treating young people when they become unwell.

### **Why me?**

At the moment we do not understand why some children and young people develop these liver diseases, and we would like to see whether genes are involved in the disease process. We are asking you to take part because you have been diagnosed by your doctors with one of these illnesses.

### **What will I have to do?**

- Your doctor or nurse will ask your parents or guardian to sign a form to consent to you joining the study.
- You can also sign an Assent Form to confirm that you are willing to join the study.
- You will be given a copy of this information leaflet and your signed form to keep.
- We will collect information about your medical and family history.
- We will ask you to donate two small blood samples (approximately 2 teaspoons). These blood samples can be taken at the time of your routine blood tests done in hospital, so you would not need an extra blood test. Your doctor or nurse will explain how they take the blood samples..
- We will also ask you to fill in a questionnaire, or your parents or guardian can do this for you.

### **Where will the study take place?**

Your doctor will see you at your next hospital appointment for your liver care. The blood samples will be taken at the hospital.

### **Do I have to join?**

No, it is up to you. It's ok if you don't want to take part and won't affect the medical care you receive. Otherwise you or your parents can just fill in the questionnaire. This will also give us valuable information about your liver disease.

### **I have already joined the study. Why are you contacting me again?**

We are contacting you again, to ask your parent or guardian to sign the latest version of the consent form. We would also be grateful if you could sign another assent form, if you are happy to do so. We may also ask you to give another blood sample, to enable us to carry out more research.

**Who is running and paying for the study?**

The UK PSC Study is run by researchers and administrators who are supported by money from the National Institute for Health Research's (NIHR) Birmingham Biomedical Research Centre, as well as from companies developing new drugs for patients. UK PSC is led by Dr Palak Trivedi, a liver doctor and researcher from the University of Birmingham.

More information on the UK PSC Study is on the study website, [www.uk-psc.com](http://www.uk-psc.com)

**Who has reviewed and approved the study?**

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, before it can begin. They check on the way in which research projects are run and ensure that patients are fairly treated and protected.

The UK PSC Study has been reviewed and approved by the Cambridge South Research Ethics Committee (REC reference 08/H0305/45).

**Will I receive any money for taking part?**

No, you will not be paid for taking part in this study or receive payment for any travelling costs, as you will participate during one of your routine hospital visits for your liver disease.

**What happens to information about me?**

Your information will be kept on a research database. Only people working with us on the UK PSC Study will be able to access the database. Your information will be stored under a special number, rather than your name and personal details.

We have given your parents or guardian more information on the storage of your information and on how we can share your health information with other researchers. This is explained in the UK PSC Parent/Guardian Information Sheet version 2.

**Will anyone know I'm doing this?**

No-one apart from your family, your own doctors, and our researchers will know you are taking part. Your sample will be given a special number and the scientists who study your blood samples will not know who it came from.

**What will happen to any samples I give?**

We will store your samples in the laboratory and may run a number of tests, including looking at your genetic material (DNA). We may store your samples for a long period, to use them in future research. We may also obtain health information about you from your medical records. We have given your parents or guardian more information about this and they will agree to this when they sign the study consent form .

**What if I change my mind about taking part?**

You can change your mind about taking part in the study at any time and don't have to tell us why. You can tell your doctor or nurse or ask your parents to let us know. You will still see your doctor for hospital appointments if you need to.

**How could taking part help me?**

The study may not help you, but the information we obtain may improve the way we treat and care for other children with autoimmune liver disease and adults with PSC in the future.

**What happens if something goes wrong?**

It is unlikely that you will be harmed by taking part in this study. We have given your parents or guardian information about what to do if you are harmed because of poor or incorrect care by the research team.

If you are unhappy with the way you have been treated during the study, you or your parents can contact the study Project Manager, < insert name>, ([ukpsc@uhb.nhs.uk](mailto:ukpsc@uhb.nhs.uk); Tel: 0121 371 8101). You can also speak to the Patient Advice and Liaison Service at your hospital.

**What happens now?**

If you decide to take part we will ask you to sign an Assent Form, to confirm that you wish to join the study. Your parents or guardian will also sign the consent form, to agree to you taking part.

You will be given a copy of this leaflet and copies of your signed Assent and Consent forms to keep.

**Who can I contact for further information?**

If you have any questions, please ask your doctor or nurse. If they do not know the answers, you or your parents or guardian can contact the UK PSC team



([ukpsc@uhb.nhs.uk](mailto:ukpsc@uhb.nhs.uk); tel: 0121 371 8101). More information is available on the study website [www.uk-psc.com](http://www.uk-psc.com).

### **Will you be in touch with me again?**

In the future we may contact you to invite you to take part in other research into autoimmune liver diseases that might interest you. We will explain the study and what is involved to you and your family. You will be able to decide if you want to take part or not.

Thank you for reading this. Please ask any questions if you need to.