PATIENT INFORMATION SHEET

Investigating the cellular mechanisms of inflammatory liver disease (with *stored* liver tissue)

PART 1

Invitation

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

PART 1 tells you the purpose of this study and what will happen to you if you take part.

PART 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Liver disease is a growing cause of death and illness and costs society tens billions of pounds each year through health and social costs. Obesity and alcohol consumption are the main drivers of the rising tide of liver disease but whatever the underlying cause, the process in the liver is similar with chronic inflammation leading to scarring and ultimately cirrhosis and sometimes liver cancer. A clear understanding of the processes that lead to this mainly irreversible liver damage is essential in order to direct treatments to reverse this condition. However, we currently have a limited appreciation of the detailed interactions that take place between immune cells within the human liver.

This study aims to set up 2 important platforms to help investigate this issue. Firstly, the development of a bank of samples of blood, urine, stool and liver tissue from patients with a range of liver diseases on which to perform future ethically approved studies. Secondly, the formation of a patient/public involvement group which will help direct future research and establish priority areas for further work.

Why have I been chosen?

You are a patient of the South West Liver Unit at Plymouth Hospitals NHS Trust and have been identified by the clinical team as having an inflammatory liver disease.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason. If you withdraw, unless you object, we will still keep samples you have donated and records relating to your condition, as

these are valuable to the study. A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive

What will happen to me if I take part?

You will receive the same medical and nursing care whether you choose to take part or not. This is because we are not testing a new drug but are looking at what is happening within your blood, liver and immune cells. If you agree to take part we will ask you to sign a consent form after answering any questions you might have.

We will ask you to complete a short questionnaire regarding your general health and lifestyle and we will record relevant details from your medical history, blood tests and X-ray tests in a secure database in a pseudonymised form. This means that your samples and data will be assigned a unique code number, and the authorised investigators will be able to link this to your medical record, but no directly identifiable details will be held on research databases or on stored samples. You will be asked to provide a stool and urine sample as well as a blood sample for this study, which will be timed to be taken along with other routine bloods (meaning no extra needle stick). You may be asked to provide additional urine or stool samples or have additional blood samples to be taken at later times if your medical condition changes. Again, these will be timed to be taken with other routine blood tests at most on a yearly basis.

Finally, if you have ever had a liver biopsy or have any stored liver tissue from previous operations in the Department of Pathology at Derriford Hospital, we ask that you allow the use of any material surplus to clinical requirements for the purpose of this study.

You will not be asked to attend any extra clinic appointments but will receive standard clinical care for your liver disease.

You will be asked if you wish to participate as part of the patient/public involvement group for inflammatory liver diseases. This is a completely optional and voluntary part of this study. This will involve attending group meetings at Derriford Hospital with other interested patients for which travel and parking expenses will be reimbursed. As part of this group you will help design patient information sheets, consent forms and other materials for future studies and will be asked to develop a patient questionnaire to determine patient priorities for liver disease research. You will be involved in undertaking interviews to identify these research priorities and raising awareness of liver disease by engagement with the media. You will be involved in dissemination of research findings. This group will be involved in the development of revised care pathways, guide future research questions and experiments to be performed on samples stored.

What do I have to do?

If you agree to take part in the study all you have to do is sign the consent form. You will be cared for as a usual patient of the South West Liver Unit and Plymouth Hospitals NHS Trust. You will need to complete a short health questionnaire. We will arrange for the stool and urine samples to be collected and extra blood tests to be taken at the time of a routine blood test. If you have a previous stored liver sample in the Department of Pathology we will arrange to use it for the purpose of this study at a suitable time.

If you wish to be part of the patient/public involvement group we will ask you to attend a number of meetings (up to 12 over 2 years and then less frequently) at Derriford Hospital for which travel and parking expenses will be reimbursed.

What is the drug / treatment / procedure that is being tested?

We are not testing any drug, treatment or procedure in this study. We are only using your blood and liver samples to investigate your immune system to find new targets to treat inflammatory liver diseases.

What are possible disadvantages and risks of taking part?

You will always receive standard clinical care for your liver condition at the South West Liver Unit and Plymouth Hospitals NHS Trust. The extra blood tests you will provide will not cause you any harm and will be taken at the same time as other routine blood tests using the same needle.

You will not have to undergo any additional clinic appointments, treatment, tests or procedures as part of this research study.

What are the possible benefits of taking part?

This study will not directly help you but the information we get might help improve the treatment of people with inflammatory liver diseases. If you become part of the patient/public involvement group you will become an important part of the research community especially in forming a link with other patients and in guiding future research in the field of liver disease.

What happens when the research study stops?

Your anonymised information and any unused samples you have donated will be stored securely for 25 years from the time of donation and for a further 5 years after the close of the study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

Contact Details

Your Research Team

Dr David Sheridan, Associate Professor of Hepatology	Tel: 01752 432724
Prof Matthew Cramp, Professor of Hepatology	Tel: 01752 432724
Dr Ashwin Dhanda, Academic Clinical Lecturer in Hepatology	Tel: 01752 437410

Your Research Nurses

Linda March and Sue Inness, Hepatology Research Nurses	Tel: 01752 432644

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2

What will happen if I don't want to carry on with the study?

You can withdraw from this research study at any time, without affecting the standard of care you receive in the future. Anonymised information already collected will still be used and any stored blood or tissue samples that you have provided will be stored anonymously and used for this study.

Will my part in this study be kept confidential?

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper and electronically at this hospital under the provisions of the 1998 Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a study number, which will be used as a code to identify you on all study forms. Data and samples using only your unique study number will be held within Plymouth University Peninsula Schools of Medicine & Dentistry, and will only be accessible to the research team.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form may be sent to the Research Sponsor during the course of the study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.

If you withdraw consent from further study treatment, unless you object, your data and samples will remain on file and will be included in the final study analysis.

In line with Trust policy, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

With your permission, your GP and other doctors who may be treating you, will be notified that you are taking part in this study.

Data and your samples collected during the study may be transferred for the purpose of (processing, analysis, etc) to associated researchers within/outside the European Economic Area. Some countries outside Europe may not have laws which protect your privacy to the

same extent as the Data Protection Act in the UK or European Law. The Sponsor of the trial will take all reasonable steps to protect your privacy.

Informing your General Practitioner (GP)

We will inform your GP that you have participated in this study. In addition, we may contact your GP during the course of the study. This will only be done if we are unable to contact you via the details you have provided to enquire about your health in the future, or if the study identifies incidental findings that may be relevant to your health. If you do not wish us to contact your GP you may still take part in the study and we will respect your wishes.

What will happen to any samples I give?

Your stool and urine samples will be stored for future analysis. We intend to look at certain components of the urine and stool including your natural gut bacteria to find out whether these can be related to your liver disease. The blood that we collect will be taken at the same time as you are having routine tests and will be put into a tube labelled only with a number and no other personal details. It will be taken to a research laboratory for analysis. Some of the blood or its components (eg plasma, DNA, immune cells) may be stored for analysis in the future. Again this will only be identified by a coded number and only be traceable to you via the chief investigators database (pseudonymised). The liver tissue will have previously been taken as part of your clinical care. These liver samples may be stained with special stains so that we can work out the type of cells causing the inflammation or cells may be removed from the tissue for separate analysis. All tissue used for the research will be coded by a number with no other personal details to identify it as belonging to a particular person. All samples will be held securely by Plymouth University Peninsula Schools of Medicine & Dentistry, in the John Bull Building. Pseudonymised samples and linked clinical information may be shared with collaborating researchers both within and outside the UK for other studies to be performed.

Will any Genetic testing be done?

Your DNA and genes may be studied to help identify important targets for future investigation. Any testing will be completely anonymised so we will never be in a position to give you, your doctor or anyone else, any specific results relating to the genetic analyses. This means that your participation in the study should not be considered to indicate that you have undergone a clinical genetic test, and therefore there are no implications for insurance or other legal purposes for you.

What will happen to the results of this study?

The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication.

Should you wish to see the results, or the publication, please ask your study doctor.

Who is organising and funding this clinical study?

This study is organised by Plymouth Hospitals NHS Trust and Plymouth University and is funded by charitable donations from Plymouth Hospitals NHS Trust.

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 your interests. This study has been reviewed and given favourable opinion by NRES Committee London – City Road & Hampstead Research Ethics Committee.

Contact for further information

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the drug(s)/procedure(s) involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

Alternatively if you or your relatives have any questions about this study you may wish to contact one of the following organisations that are independent of the hospital at which you are being treated:

If you have concerns while on the study

Whilst it is something we hope will not happen, if you have concerns about any aspect of research please speak to the researchers using the contact details you will have been provided with. Alternatively, you may wish to contact the hospital's Patient Advice and Liaison Service (PALS).

PALS offers support, information and assistance to patients, relatives and visitors and will:

- Provide information about hospital services.
- Offer advice on where to go to get health information.
- Help with problems that you haven't been able to sort out with staff on a ward or in a clinic.
- If you want to make a complaint - advise you how to do so.
- Tell you about independent organisations that can help you with a complaint.
- Listen to your views on how we can improve our services, and pass this on to the appropriate people for action.

PALS can be contacted at:

Patient Advice & Liaison Service

Level 7

Derriford Hospital

Plymouth

PL6 8DH

Email: plh-tr.PALS@nhs.net

If you decide you would like to take part then please read and sign and date the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.