Investigator: [name] **Centre number**: [number] **Contact for queries** If you have any questions about this study, you can contact: **Daytime:** [name] on [phone number]	**Clinic name** **Address line 1** **Address line 2** **Postcode** **Phone:**

ADULT PARTICIPANT INFORMATION SHEET

STOP-HCV Prognostic biomarkers in HCV cirrhosis

Participant Initials: _____ Participant's Study Number _____

We would like to invite you to become part of the STOP-HCV Cirrhosis study by donating blood and urine samples and allowing us to collect medical information about you. Before you decide we would like you to understand what this study is and how you would be involved. If you are willing to consider participating, one of our team will go through the information sheet with you and answer any questions you have. We suggest this should take about 30 minutes.

Talk to others about the study if you wish and ask us if there is anything that is not clear. You will be given as much time as you want to make a decision.

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.

PART 1

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to investigate whether there are new (or existing) diagnostic tests which, when measured repeatedly over time, could be used to predict which patients with HCV cirrhosis progress to specific symptoms (including fluid in the abdomen, confusion and bleeding) that indicate the development of more severe disease within 5 years of follow up.

More information is given about this below.

WHY HAVE I BEEN INVITED TO TAKE PART?

This study is being set up across many centres in the UK.

You have been asked to join this research study because you have been infected with hepatitis C virus (HCV) and have cirrhosis of the liver. You have already consented to join the HCV Research UK study and are currently seeing a doctor for management of your cirrhosis. About 1,000 participants like you, will be asked to take part.

DO I HAVE TO TAKE PART?

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You are still free to

withdraw at any time and without giving a reason. If you decide not to take part, or withdraw at any time, this will NOT affect the standard of care or treatment you receive.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

As part of your normal care, you will be asked to attend the clinic on a number of occasions. If you join our Research Cohort, the information you provide at these clinic visits will be recorded and stored in our database along with results of any laboratory tests. We will ask you if we may take some extra blood sample(s) and a urine sample which will be analysed and then stored for future use in a biobank. We will also ask for your permission to use the remains of any samples that are/have been taken from you as part of your routine clinical care, but which are not needed for diagnostic purposes. The number of visits you make to the clinic and the care you receive at each visit should NOT be altered by your agreement to participate in this study.

The Study Doctor or another member of his/her team will explain the details of the study. If you agree to take part, you will be asked to sign the consent form.

Once you have signed the consent form, the clinic staff will:

- Ask you about your current health and any medications you are taking
- Ask you to complete a questionnaire about your alcohol intake. You will need to complete one each year for the next 4 years.
- Take extra blood sample(s) to be analysed. A total of 5 samples (25mls / 5 teaspoons each) will be taken during the study – one at the beginning and another one each year for the next 4 years. These samples will be taken at the same time as any routine blood tests are done so that it will not require you to have extra needles.

  We will perform tests on this blood (including some genetic tests) that are not currently part of your routine clinical care.
- Collect urine samples (20mls) to be analysed. A total of 5 samples may be taken during the study – one at the beginning and another one each year for the next 4 years.

  We will perform tests on this urine that are not currently part of your routine clinical care.
- Collect data on any scans or investigations (including ultrasound, CT, MRI, endoscopy and fibroscan) that are performed as part of your routine clinical care.
- Collect data each year for the next 4 years to monitor your cirrhosis.

WHAT DO I HAVE TO DO?

You must be willing to sign the attached Consent form.

You can still take part in other studies as long as you let the team know you have enrolled in this study as well.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS OF TAKING PART?

There is no increased risk to your health. The extra blood needed for this research study will be taken at the same time as another routine blood sample.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

The information we get from this study may help us to improve our care of patients with hepatitis C virus infection and cirrhosis. If we find out anything new, your study doctor will be able to tell you if your care will be affected.

WHAT ARE THE COSTS OF TAKING PART?

There should be no costs attached to taking part in this study. You may be reimbursed for any extra travel expenses if you need to make a special visit to the hospital for the study.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1.

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

PART 2

WHAT HAPPENS IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Your study doctor will inform you immediately about all new findings which are made available to him/her which could be of importance to you or that may affect your willingness to continue participating. Based on this you can then reconsider your decision to continue participating in this study.

WHAT WILL HAPPEN IF I DO NOT WANT TO CARRY ON WITH THE STUDY?

You can withdraw at any time. If you withdraw, any data or stored samples will continue to be used unless you specifically request to your study doctor that you do not want them to be used.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Yes. 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 your treating hospital and the main hospital site managing this research 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 trial number, which will be used as a code to identify you on all trial forms.

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.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 15 years. Arrangements for confidential destruction will then be made.

Data and 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.

By signing the consent form you are authorising your study doctor to disclose relevant details of your medical history in strict confidence. Your consent to the use of study data does not have a specific expiration date, but you may withdraw your consent at any time by notifying the Study Doctor. If you withdraw your consent STOP-HCV may still use data and samples that were shared with it before you withdrew your consent.

You have the right to request information about Study Data held by the Study Doctor and STOP-HCV. You also have the right to request that any errors in the data be corrected. If you wish to make a request, then please contact the Study Doctor, who can help you contact STOP-HCV if necessary.

Involvement of your General Practitioner/Family Doctor (GP)

It will not normally be necessary for the Study Doctor to inform your GP that you have decided to take part in this study. However, we will ask you to agree to us contacting your GP by signing the consent form in case this becomes necessary. If you have any objections to your GP being contacted please speak to your Study Doctor.

WHAT WILL HAPPEN TO ANY DATA AND SAMPLES THAT I GIVE?

The data and samples donated will belong to STOP-HCV and HCV Research UK. Your clinical data will be stored in a research database. Access to such data will be limited to those involved in your direct care, the project co-ordinator and the data manager for HCV Research UK. After the study is completed, any left-over blood samples will be stored indefinitely in a biobank. The blood and data held in the research biobank and database will be available to both academic and commercial groups for further research in the future. The specific nature of the research is not known fully at this time and will vary as new ideas and theories continue to be formed and need to be tested. The research may include genetic tests and other studies of the factors associated with different disease outcomes. It may be used to look at how factors such as age, obesity and alcohol consumption affect disease progression. It will not involve cosmetic testing or any other consumer goods testing.

All the testing done on your samples, now and in the future, will be performed for research and development purposes only. It is not the purpose of this research to provide you with test results. They will not be used for your medical care or to make a diagnosis about your health. However, occasionally research on samples can reveal unexpected information. In that event, with your consent, the information may be passed to your doctor and the samples that have been taken may be made available for further tests to help with your treatment. The results from this research and any future research may be used for commercial purposes. You will have no right to this property or to any share of the profits that may be earned directly or indirectly as a result of this or any future research. However, in signing this form and donating sample(s) for this and any future research, you do NOT give up any rights that you would otherwise have as a participant in such research.

If you withdraw your consent at any time, we will stop collecting data from you and you will not be asked for any more blood. If you lose the ability to give consent during the study or if you withdraw consent, the samples and data already collected will continue to be used unless you or your family specifically request that they are destroyed.

WHO IS ORGANISING AND FUNDING THIS RESEARCH?

The Medical Research Council is funding this research. The study is being run by the Steering Committee of STOP-HCV.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Black Country Research Ethics Committee.

WHAT IF THERE'S 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 questions. The Research Team responsible for this research can be contacted at [Local Address], telephone [Number].

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 or you can contact Patient Advice and Liaison Service (PALS), [Local Address] Telephone [Number].

In the event that something goes wrong and you are harmed during the research 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.

Signing this form does not take away any of your rights. You still have rights as a participant in a research study. If you have any further questions about this information you can contact:

Doctor's Name _____ Telephone Number_____

Nurse _____ Telephone Number_____