A joint venture between The University of Melbourne and The Royal Melbourne Hospital

Participant Information Sheet/Consent Form

Title	Hepatitis and liver cancer outcomes in general practice: an intervention collaboration (HepLOGIC)
Short Title	HepLOGIC pilot and feasibility study
Protocol Number	HREC 2020.157
Project Sponsor	Melbourne Health
Principal Investigator	Professor Benjamin Cowie Director, WHO Collaborating Centre for Viral Hepatitis Melbourne Health

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this survey because you have been identified as a potential user of the HepLOGIC intervention that is currently being tested by your general practice clinic as part of our pilot and feasibility study.

We want to understand the experiences of health professionals and other primary care staff who have used the HepLOGIC intervention and collect feedback or suggestions for optimising the intervention and its implementation in general practice.

2 What is the purpose of this research?

The HepLOGIC intervention is a Clinical Decision Support System that has been designed to support general practice in the delivery of guideline-based care to people living with viral hepatitis and reduce their risk of liver cancer. We are currently testing HepLOGIC in your clinic.

We want to make sure that this intervention is useful and acceptable to health professionals and other relevant staff working in primary care.

3 What does my participation in this research involve?

You will participate in a one-on-one interview with the researcher, either face-to-face or via video/teleconferencing. You will be asked about your experiences and feedback in relation to the implementation and use of the HepLOGIC intervention in your clinic. The interview will run for up to one hour, depending on the detail you provide in your responses.

The interviewer will audio-record the interview and take handwritten notes. You will be asked to sign a consent form for face-to-face interviews. For video/teleconference interviews you will be asked to provide verbal consent, which will be included in the audio recording of the interview.

Your participation is completely confidential. Your personal details, such as your name, address or place of work will not be included in any of our reports or publications.

4 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and then change your mind, you may withdraw from the project at any point up to or during the interview. However, you will not be able to withdraw your interview responses following the completion of the interview.

5 What are the possible benefits of taking part?

Your participation will contribute to the development of a clinical tool that will improve the detection and management of chronic viral hepatitis in general practice. Possible benefits may include that you personally come away with an improved understanding of the risks and management of chronic viral hepatitis, and that health outcomes for people living with viral hepatitis are improved in the future.

6 What are the possible risks and disadvantages of taking part?

We believe that any risks to participants in this study are minimal. It is possible that you might feel uncomfortable discussing factors about how viral hepatitis and liver cancer risks are managed in general practice or be concerned about judgment from others. The study will be facilitated by experienced researchers who will be able to mitigate such risks.

If you have any questions or concerns regarding the interview or the study, please contact the researchers using the contact details at the end of this form.

7 Can I withdraw from this research project?

You are free to terminate your participation at any point up to or during the interview, and any data, notes or recordings collected by the interviewer will be destroyed. You will not be able to be withdraw after the interview has concluded.

Your decision not to participate will not impact on your relationship with the research group or Melbourne Health.

8 What happens when the research project ends?

A final report will be compiled at the end of the project and provided to your clinic. It will also be made available to you upon request.

The outcomes from this project may be published academic journals or presented at conferences.

Part 2 How is the research project being conducted?

9 What will happen to information about me?

By signing the consent form, or providing verbal consent within the interview, you consent to the research team collecting and using the information that you provide to us during the interview for the research project.

Audio-recordings and transcribed information will be securely stored by Melbourne Health for a period of at least seven years, after which time it will be destroyed.

Your contact details have been collected for the purpose of organising the interview. These details will be kept securely and then deleted once the study is complete. They will not be kept by the researchers for any other purpose.

It is expected that the results of this research project will be published and/or presented in a variety of forums. No identifying information about participants will be reported, published or disseminated with the study findings.

10 Who is organising and funding the research?

This study is being conducted by Melbourne Health and has been funded by the Victorian Cancer Agency.

The study is led by Professor Benjamin Cowie, Director WHO Collaborating Centre for Viral Hepatitis at the Royal Melbourne Hospital and Peter Doherty Institute for Infection and Immunity.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

11 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Melbourne Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

12 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact:

Research contact person

Name	Amelia Savage
Position	Research Project Manager, WHO Collaborating Centre for Viral Hepatitis
Telephone	(03) 9342 9483
Email	whoccvh@mh.org.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Director Research Governance and Ethics, Melbourne Health
Position	Complaints Manager
Telephone	(03) 9342 8530
Email	research@mh.org.au

Consent Form

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Declaration by Participant

I have read the Participant Information.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I may withdraw prior to the interview starting or any time while the interview is underway, but that it will not be possible to withdraw my responses once I have completed and left the interview.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Researcher† (please print) _____

Signature _____ Date _____

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

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Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my relationships with the researchers or Melbourne Health.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

Declaration by Researcher[†]

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Researcher (please print) _____

Signature _____ Date _____

[†] An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.