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

Participant Information Sheet/Consent Form

Title	Investigating how mothers with hepatitis B understand and experience mother to child transmission interventions in Victoria
Short Title	Hepatitis B perinatal project
Protocol Number	HREC 2019.318
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

Thank you for your interest in this research project. This form will give you information about the research so you can decide if you would like to take part in this research. It explains what is involved in taking part in the research.

You are invited to take part in this research project because you are over 18 years of age, **and**

a. A women with hepatitis B **and**
b. Have given birth in Victoria in the last 10 years
c. Able to provide informed written or verbal consent

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. If you decide you want to take part in this research project, you will be asked to sign the consent form below or record your agreement before the interview. You will be given a copy of this Participant Information and Consent Form to keep.

We value your contribution and also recognise that you may have incurred expenses in participating in the interview and so you will be offered a $50 gift voucher at the end of the interview.

2. What is the purpose of this research?

The purpose of this research is to investigate how mothers with hepatitis B understand and experience interventions seeking to prevent the transmission of hepatitis B from mother to child in Victoria. The study seeks to gain a better understanding of the lived experience of mothers with hepatitis B during and after pregnancy in preventing hepatitis B mother to child transmission.

3. What will I be asked to do?

You will be invited to participate in a 45 minutes one-on-one interview with the researcher either face to face or over the phone. In the interview, you will be asked questions about your experience with hepatitis B and giving birth. For example, you will be asked some questions about what information you were given about hepatitis B during or after pregnancy and birth and how you understood this information. What information was helpful and what could have been improved.

An interpreter will be provided if you or the interviewer requests one. The interview will take place at an agreed location that is suitable for you. With your consent, the interview will be audio recorded and the interviewer will take hand-written notes. You can ask the recording to be stopped at any-time during the interview. The audio recording will be destroyed after it has been transcribed. No images or videos will be taken.

Your participation is completely confidential. Your personal details, such as your name and address will not be shared with other people or included in any reports or publications and will be removed from the transcription. We will not tell anyone that you have taken part in the interview. Only the named researchers will have access to the audio-recording and notes from the interview.

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 later change your mind, you may withdraw from the research at any time and your interview responses will not be used in the study.

5. What are the possible benefits of taking part in this research?

There is no direct benefit in taking part in this study, but you may appreciate sharing your experience and opinions to improve care provided to mothers with hepatitis B. You may also like to help build new knowledge about the needs and challenges of mothers with hepatitis B and their baby in the health services. Any health care you are receiving will not be affected if you choose not to participate in the interview.

6. What are the possible risks and disadvantages of taking part in this research?

We do not anticipate that there are any physical risks in taking part in this study, although some questions we ask might be upsetting or stressful. You are under no obligation to answer any questions that you do not want to answer. If any of the questions we ask about your experiences are upsetting or stressful; you do not have to answer them and you can stop the interview at any time. We can help you find someone to talk to with your permission, such as counselling services or your doctor.

We understand that hepatitis B-related stigma and discrimination can negatively impact on the health and wellbeing of people with hepatitis B. The researchers are experienced working with communities affected by hepatitis B and are trained to be sensitive and culturally safe. The interviewer will also address any questions regarding hepatitis B and provide standard hepatitis B resources, such as brochures.

This research is not about illegal activities, but our discussions may show that illegal activities have taken place - these will only be disclosed where required by law. All responses are anonymous and the researchers will not disclose any information without your consent, unless they are required to by law. Even so, you should think carefully about anything you tell us that may relate to illegal activities or behaviour.

If you have any questions or concerns before or after the interview, please contact the researcher Nafisa Yussf on 9342 9377 or the Hepatitis Victoria information line on 1800 703 003, or your local doctor.

7. Can I withdraw from this research project?

If you do agree to take part in this research, you may still withdraw at any point prior to or during the interview. After the interview, you can withdraw after 2 weeks of the interview. If you opt-in to review your transcription, you will have 2 weeks to review (and withdraw) after the transcription has been sent to them. If you want to withdraw from the study, contact the researcher: Nafisa Yussf on 0497 589 200.

There is no penalty or consequence for withdrawing from the research project and your withdrawal will not affect care provided to you in the future.

What happens when the research project ends?

The results of this research project will be published in a report. It may also be published in a peer-reviewed academic journal and presented at conferences. No names of people in the study will be used.

Part 2 How is the research project being conducted?

8. What will happen to information about me?

By agreeing to participate in this research, 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 will be destroyed after they have been transcribed by a transcription agency, and the transcribed information will be "de-identified" (so that it will not include your name or other personal identifying information). The transcribed information will be stored safely by Melbourne Health for a period of at least five years, after which time it will be destroyed. Your name or contact details will not be linked to any of the information you provide during the interview, and will not be available to other researchers in the future.

The results of this research project will be published in a report. It may also be presented at conferences and published in peer-reviewed academic journals. In any publication or presentation, your information will be de-identified.

You can opt-in to receive the research findings and report.

Your contact details may have been collected for the purpose of organising the interview. These details will be deleted from our contact list once the interview is complete, and not kept by for any other purpose (unless you have opted-in to receive the research report).

9. Who is organising and funding the research?

This research project is being conducted by Melbourne Health and is part of a larger study funded by the Department of Health and Human Services. Hepatitis Victoria and Burnet Institute are partners in this project. Hepatitis Victoria is a community organisation with extensive experience working with people with hepatitis. Burnet Institute is a research organisation.

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

10. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a 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.

11. Further information and who to contact

If you would like to participate in this research or would like further information, please contact:

Name	Nafisa Yussf
Position	Research Project Manager
Telephone	0497 589 200
Email	Nafisa.yussf@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:

Who can I contact if I have any concerns about the project?
If you have any concerns about how this research is being conducted, please contact the complaints Manager.

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 or someone has read it to me in a language that I understand.

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 after interview is transcribed.

I understand that I will be given a signed copy of this document to keep.

Do you give consent to be audio-recorded?

Yes ☐ No ☐

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form

Witness to the informed consent process
Name (please print) _____
Signature _____ Date _____
* Witness must be 18 years or older.

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 participating in the above research project and understand that such withdrawal will not affect my routine care, or 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.