(Version No.1 4/7/2013)

Consent form and information sheet

Study title:

A multi-center prospective study on the evaluation of paternal, maternal and obstetric factors leading to the hepatitis B immunization failure in Hong Kong

You are being invited to take part in a research study. Before you decide, 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 friends, relatives and your family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study:

Globally, hepatitis B virus (HBV) infection is the most common form of chronic hepatitis. According to the World Health Organization, 600 000 people die each year due to HBV and 25% of chronic carriers since childhood later die from cirrhosis or liver cancer. 90% newborns will become chronic carriers after HBV exposure. In Hong Kong, combined use of active vaccination and passive immunisation with hepatitis B immunoglobulin (HBIG) was incorporated into the local childhood vaccination programme in 1989. It was found that despite HBIG and vaccination, there was a vertical transmission rate of 2.5%. Testing for anti-HBsAb and for HBsAg at 9 to 18 months of age can ensure immunity and to pick up chronic carriers. However, the hepatitis status of the newborn from hepatitis B carrier mother is not routinely performed after vaccination. This may potentially lead to a group of children with chronic hepatitis B infection or non immune children. We would like to carry out a study to look into possible factors leading to immunoprophylaxis failure and to look at the prevalence of immunoprophyaxis failure in Hong Kong.

Why have I been chosen?

All patients over or equal to 18 years old, who herself or her partner is a hepatitis B carrier, who was booked for antenatal care in Queen Mary Hospital, Kwong Wah Hospital, Queen Elizabeth Hospital, Pamela Youde Nethersole Eastern Hospital and Tuen Min Hospital, will be recruited. A total of 724 hepatitis B carrier mothers will be included in the study in group 1. 550 male partners of hepatitis B negative mothers will be screened for hepatitis B in group 2.

Do I have to take part?

It is up to you to decide on whether to take part. You will be asked to sign the consent form if you have decided to join the study. You can always change your mind and withdraw anytime you want without giving any reason. This will not affect the standard of your care you receive.

What will happen to me if I take part?

In group 1, mothers' blood will be drawn at the time of recruitment (15ml blood) and at 28-30 weeks (test for hepatitis markers, 10ml blood)) and at 35-37 weeks (sample to be saved for future analysis, 10ml blood)). You and your doctor will not know the result of tests.

In group 2, male partners' blood will be drawn at the time of recruitment (test for hepatitis B markers, 15ml blood). They will be recruited if they are confirmed hepatitis B carriers. Mothers' sample at the booking visit will be tested for HBV DNA. Male partners will be excluded if the mothers are positive for HBV DNA.

Mothers will be followed up in respective hospitals/ maternal child health centre. The care will not be different from other women. Mothers' antenatal, intrapartum and postnatal details will be recorded through follow up or phone interview (around 5 minutes).

Mothers' cord blood (15ml blood) will be saved for testing for hepatitis B status. The cord blood saved cannot be retrieved for other purposes. If cord blood saving is not possible, we will take the babies' blood at birth before the hepatitis B vaccination. Babies' blood will be drawn at 9-12 months to test for babies' hepatitis B status (15ml blood). Blood samples at birth and 9-12 months will be saved for future analysis or genetic testing.

What are the benefits of taking-part?

The baby will be offered blood test at 9-12 months of age and will be referred to Queen Mary Hospital for further follow-up if he or she was found to be hepatitis B positive status despite giving vaccinations.

What are the risk of taking-part?

Blood taking is generally considered safe. The hepatitis B status may be revealed during the study which may lead to clinical/ psychological impact. (ie. need self arranged regular follow up, insurance impact). There is no established guideline to manage neonatal suffering from chronic hepatitis B infection. However, they will be followed up by Paediatrics Unit for further management.

Confidentiality

You have the rights of access to personal data and publicly available study results, if and when needed.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any

way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Privacy Data or his office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By consenting to participate in this study, you expressly authorize:

- the principal investigator and his research team and the ethics committee responsible for overseeing this study to get access to, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process; and
- the relevant government agencies (e.g. the Hong Kong Department of Health) to get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements

What will happen to the results of the research study?

The results of the research will be published in a medical journal once the study is over and you will not be identified in any report/publication.

Who is organizing and funding the research?

Should you have any queries about this study, please feel free to contact

Dr. KW Cheung (Queen Mary Hospital) Tel: 22555940

Thank you for taking part in this study.

PATIENT CONSENT FORM

Title of Project: A multi-center prospective study on the evaluation of paternal, maternal and obstetric factors leading to the hepatitis B immunization failure in Hong Kong.

Name of Researcher: Dr. KW Cheung (Queen Mary Hospital)

Please initial box

1. I confirm that I have read and understood the information sheet dated __/__/__ for the above study and have had the opportunity to ask questions. □

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. □

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. □

4. I understand the all samples will be saved and used for future analysis □

5. I understand and agree the blood samples or cord blood may be obtained from me, my partner or the infant □

6. I agree to take part in the above study. □

You will be assigned to (*please tick the box)

□ Group 1: Hepatitis B carrier mothers

□ Group 2: Male partners of hepatitis B negative mother (QMH only)

_____	_____	_____
Name of mother	Date	Signature
_____	_____	_____
Name of father (if applicable)	Date	Signature
_____	_____	_____
Name of investigator	Date	Signature
_____	_____	_____

Name of Witness Date Signature