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IRB APPROVED

September 11, 2020

MERCY MEDICAL CENTER  
Baltimore, MD 21202

**Study Title:** COMPARISON THE SEROCONVERSION RATE BETWEEN TWO-DOSE AND THREE-DOSE REGIMENS OF HEPLISAV-B AMONG PATIENTS WITH CIRRHOSIS, A RANDOMIZED CONTROL PROSPECTIVE STUDY.

**Investigator name and address:** Paul Thuluvath, M.D., 301 St. Paul Place, POB#718, Baltimore, MD 21202  
**Daytime/24-hour Telephone Number:** 410-332-9308  
**MMC#: 2020-24**

**KEY INFORMATION:** Taking part in this research study is up to you. You can decide to not take part. If you decide to take part now, you can change your mind at any time and leave the study. The following key information is to help you decide whether or not to take part in this research study. Detailed information regarding this research study has been included following this section.

**PURPOSE:** The purpose of this research study is to compare the efficacy of two-dose regimen versus three-dose regimen of Heplisav-B in patients with cirrhosis. The nationally recommended regimen includes two doses given at 0 and 4 weeks which only works in 46.3% of cirrhotic patients. The best approach to HBV vaccine nonresponse is repeating the vaccine series at the same dose and using the same route in noninfected individuals. We are trying to evaluate if three doses given at 0, 4 weeks and 8 weeks will work better than the two-dose regimen. You have been asked to participate in this study because you have cirrhosis

**OVERVIEW OF PROCEDURES:** If you agree to participate, you will be randomly assigned (like tossing a coin) to receive two doses 0 and 4 weeks or three doses of Heplisav-B at 0, 4 weeks, and 8 weeks. We will check your blood work at the end of the vaccine series to check whether you are protected against hepatitis B. Duration of participation will be up to 12 weeks after completing hepatitis B vaccine series.

**RISKS:** The side effects are minor. Most common adverse effects within 7 days are injection-site pain (usually mild), fatigue, headache or fever. These are extremely uncommon. There is always the risk of a loss of confidentiality. The confidentiality section in this form discusses how information about you will be collected, used, protected, and shared.

**BENEFITS:** We will check your protection against Hepatitis B after completing your vaccine series by checking labs for the vaccine titre. It is important to be protected against Hepatitis B, especially if you have cirrhosis. It will decrease the risk of contracting hepatitis B. Furthermore, the information gained during the study may help others in the future.

**ALTERNATIVE PROCEDURES:** If you choose not to participate in the study, you will still receive two doses of Heplisav-B.

You are being invited to take part in a research study. Your participation is completely voluntary. You are being asked to make an informed decision as to whether or not to participate in this study. The “informed consent process” will explain more about this project, including why it is being conducted, how you could be involved and detail what is involved for you to take part. It also explains how your medical information will be used and who may see it. Please ask the study doctor or study staff to explain anything you do not understand. You can discuss this study with your family, friends, and family doctor, if you wish. You are being asked if you would like to participate in this research study due to your current medical condition.

**PROCEDURES:** If you agree to participate in this research study, you will be asked to read and sign this consent form before any study procedures are done.

This study will consist of the following:

- **Initial visit:** you will receive the first dose of Heplisav-B.
- **Follow up visits:** you will receive the second dose at week 4th, and the third dose of Heplisav-B at week 8th (if you are in the three-dose group). We will check your protection against Hepatitis B by blood work 12 weeks after completing the vaccine series.

**POSSIBLE BENEFITS AND RISKS OF THE STUDY:** We will check your protection against Hepatitis B after completing your vaccine series. It is important to be protected against Hepatitis B, especially if you have cirrhosis. It will decrease the risk of developing liver cancer and decrease the risk of contracting acute hepatitis B. Furthermore, the information gained during the study may help others in the future. Besides possible minor side effects from the vaccine, there is always the risk of a loss of confidentiality. The confidentiality section in this form discusses how information about you will be collected, used, protected, and shared.

**ALTERNATIVES TO PARTICIPATING IN THE STUDY:** If you choose not to participate in the study, you still receive two doses of Heplisav-B as recommended nationally for patients with cirrhosis who are lacking immunity against Hepatitis B.

**NEW FINDINGS:** If new information or any significant new findings become available during the study that may affect your willingness to continue participation in this study, we will tell you in a timely manner. You can then decide if you still want to participate in the study. If new information arises, you may be asked to sign and date a revised consent form stating you were informed of the new information. You may contact us any time after the study ends to find out if any new information about this study has become available.

**Volunteering to be in the Study:** Participation in this study is completely voluntary. The decision is entirely up to you. If you decide to participate and later change your mind, you can withdraw from the study at any time without giving a reason. Choosing not to participate or leaving the study at any time will not result in any penalty or loss of benefits to which you are otherwise entitled or have any effect on your future medical care. If you are participating in the study but you are not participating in nutrition counselling, you can change your mind at any time and start nutrition counselling. On the other hand, if you are participating in the study and nutrition counselling, you can choose to continue in the study and stop nutrition counselling at any time.

**PARTICIPANT RESPONSIBILITIES:** If you choose to participate in this study, it is very important that you:

- Come to all scheduled visits as agreed with your doctor.
- Inform the study doctor or study staff if you decide you no longer wish to participate in the study.

**COSTS TO ME AS A RESULT OF PARTICIPATING IN THIS STUDY:** There will be no charge to you for your participation in this study.

**COMPENSATION FOR PARTICIPATION:** There is no economical compensation for participating in this study.

**CONFIDENTIALITY:** Your record of being in this study will be kept private except when ordered by law. The following people will have access to your study records:

- The study doctor and the study staff
- The Institutional Review Board (IRB)

The Institutional Review Board and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

#### **Confidentiality, Collection and Use of Study Data**

Your study doctor and study staff will collect information about you which is relevant to this study; specifically, your name, address, contact details, date of birth, medical records, health, race, and ethnicity. This collected information about you is called “data” or “study data” in this document.

#### **Confidentiality of Study Data and Key-coded Data**

For the purposes of your participation in this study and the protection of your identity, your study doctor will assign you a unique code, such as a series of numbers and/or letters. The study doctor will record the study data

collected from you in a report form that uses your assigned code, not your name. This is to protect your study data by making it anonymous for most study purposes.

The data that is recorded with your assigned code rather than your name is called “key-coded data”. The key-coded data will be entered into the study’s computer database. Your study doctor will keep a confidential list linking your subject number to your identity if there is a need for contacting you after the study is over and only authorized persons at the site will have access to this list.

Some study data will identify you (such as medical records) and the ways in which this data may be used and shared is described below.

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

**Use and Sharing of Key-coded Data:** Your key-coded data may be shared with and used by the following as noted above under the confidentiality statement. Your identity will not be revealed in any compilation, study report or publication at any time

**Use and Sharing of Study Data that Identifies You:** The use and sharing by your study doctor of study data that identifies you, such as your original medical records, are explained in the “HIPAA Authorization” section of this document titled CONFIDENTIALITY AND AUTHORIZATION TO COLLECT, USE AND DISCLOSE PERSONAL MEDICAL INFORMATION. By signing the present informed consent form, you show that you give permission for the use and sharing of this data as described in that document. You do not have to sign this informed consent form, but if you do not, you will not be allowed to participate in this study. To withdraw your HIPAA Authorization, you will need to do so in writing as described in the above-mentioned section.

**Your Access to and Correction of Study Data that Identifies You:** You have the right to obtain any initial and updated information about the study data that identifies you, as well as the right according to local law and procedures to require the correction of any errors. However, your access to this information may be delayed until the study is complete. Any medical information produced as part of the study that will affect your medical care will be disclosed to you without delay. This information, as well as the fact of your participation in this study, can also be provided or made known to your primary physician if you wish. You can discuss this further with your study doctor, who will be your primary contact person for your access rights.

**CONTACT INFORMATION:** If you have any questions, concerns, or complaints about this study, or if you have issues/injury from participation, please contact the investigator at the telephone number(s) listed on the first page of this form. If you do not want to talk to the study doctor or study staff, if you have concerns or complaints about the research, or to ask questions about your rights as a study participant you may contact Mercy Medical Center IRB, 410-332-9692. The IRB has reviewed the information in this consent form. You must consider the information in this consent form for yourself and decide if you want to be in this study.

## **THE REASON FOR INSTITUTIONAL REVIEW BOARDS AND INFORMED CONSENT**

***What is a consent form?*** The informed consent document contains information required by federal regulations. The informed consent document must be reviewed by an Institutional Review Board (IRB).

### ***What is an Institutional Review Board (IRB)?***

An Institutional Review Board (IRB) is a group of people that reviews research studies. The main goal of this review is to protect the rights and wellbeing of the human participants in research studies.

This research is being overseen by an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at 410-332-9692 if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

**AGREEMENT TO BE IN THE STUDY**

This consent form contains important information to help you decide if you want to be in the study. If you have any questions that are not answered in this consent form, ask one of the study staff. You will receive a copy of this consent form after you have signed and dated it.

I give my permission for the study doctor to use my personal health information for the purpose of this study and to disclose this information as described above within this consent form. I understand that such information will remain confidential.

\_\_\_\_\_  
Printed Name of Study Participant

\_\_\_\_\_  
Signature of Study Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

I have fully informed the participant about the study and answered all of the participant’s questions.

\_\_\_\_\_  
Printed Name of Person Conducting the Informed  
Consent Discussion

\_\_\_\_\_  
Signature of Person Conducting the Informed  
Consent Discussion

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time

**HIPAA AUTHORIZATION**

<b>PI Name:</b> Paul J. Thuluvath, M.D., FRCP	<b>MMC IRB Number:</b> 2020-24
<b>Study Title:</b> Comparison the seroconversion rate between two-dose and three-dose regimens of Hcpisav B among patients with cirrhosis, a randomized-control prospective study.	<b>IRBNet Number:</b> 1648100-1

**What is the purpose of this form?**

During this research study, the people working on the study will be collecting protected health information about you. Your health information is protected under the Health Insurance Portability and Accountability Act (“HIPAA”) and Maryland law. Under these laws, with some exceptions, Mercy Health Services, including Mercy Medical Center and its affiliated providers (“Mercy”)\* cannot use or disclose your protected health information for research purposes unless you give your permission. The research team would like to use your protected health information for the study. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers may use your protected health information, you must sign and date this form to give your permission, called your “authorization.”

You may choose not to sign this authorization form. However, if you do not sign this form, you will not be able to participate in the research study. Your decision will not affect your ability to receive standard medical care from Mercy, and you will not lose any benefits to which you would otherwise be entitled.

\* Mercy’s affiliated providers are listed within Mercy’s Notice of Privacy Practices, available at <https://mdmercy.com/about-mercy/policies-and-corporate-documents/privacy-policy>.

**What protected health information will be used and/or disclosed?**

The research team working on the study will collect information about you. This includes information learned from the procedures described in the consent form. They may also collect other information including your name, address, date of birth, medical history, or other information from your medical records (which could

include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other clinicians within Mercy, who may treat you have access to important information about your health.

**Who will have access to my protected health information?**

The research team will know your identity and that you are in the research study. Other people at Mercy, particularly your doctors, may also see or give out your information. We make this information available to your other health care providers (including providers outside of Mercy) for your safety, particularly if you are taking an investigational drug as part of this research study.

As part of the research study, the research team may disclose your information to certain individuals and entities outside of Mercy, who may need to see or receive your information for this study. Examples include:

- The research Sponsor or Sponsor’s representatives;
- Government agencies (such as the U.S. Food and Drug Administration);
- Safety monitors who oversee the study;
- Other institutions or sites participating in this study; and
- The Mercy Medical Center IRB and/or a central Institutional Review Board, which are groups tasked with protecting the rights and welfare of human research subjects.

Mercy will use and disclose your health information only as described in this form, the consent form, and in our Notice of Privacy Practices; however, people outside Mercy who receive your information may not be covered by this promise or by the federal HIPAA Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed. The results of the study may be published in scientific journals or presented at medical meetings, but your name and identity will not be disclosed in these settings.

**Does my authorization expire and can I withdraw my permission?**

This authorization does not have an expiration date. However, you may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by calling Mercy’s Privacy Officer at 410-576-LAWS (5297) or by sending a letter to: Mercy Privacy Officer, 345 St. Paul Place, Baltimore, MD 21202 If you cancel your authorization to use and disclose your health information, your part in this study will end and no further information about you will be collected. Your revocation would not affect information already collected in this study.

If you agree to the use and release of your protected health information, please sign below. You will be given a signed copy of this form.

\_\_\_\_\_  
Printed Name of Subject

\_\_\_\_\_  
Signature of Subject or Subject’s Legal Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name of Legal Representative (if applicable)

\_\_\_\_\_  
Legal Representative’s authority to act for patient (if applicable)