

To be completed by IRB office:

IRB # 09-001670 00

Consent form approved January 25, 2019;

This consent valid through January 24, 2020;

1. General Information about This Research Study

Study Title: “Hepatitis B and Hepatitis C as Risk Factors for Hepatocellular Carcinoma in African and Asian Immigrants: Role of Viral Genetics and the Immune Response”

Name of Principal Investigator on this Study: Dr. L.R. Roberts and Colleagues

A. Study Eligibility and Purpose

You are being asked to take part in this research study because you have been diagnosed with hepatitis B and/or hepatitis C and are of African or Southeast Asian descent. You may also be asked to participate in this study because you are an individual of African or Southeast Asian descent, who is free from hepatitis B and hepatitis C. This research is being done to advance the understanding of hepatitis B and hepatitis C infections in African or Southeast Asian immigrants. The overall goal of this research is to compare African or Southeast Asian patients with known hepatitis B and/or hepatitis C infections to individuals without these infections to determine the risk factors (genetic and/or immunologic) associated with both infections which could be unique for African or Southeast Asian immigrants. Infections by both viruses (hepatitis B and hepatitis C) are known risk factors for hepatocellular carcinoma (referred to as liver cancer).

As you read this form describing the study, ask any questions you have. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you decide. If you decide to participate, you may stop participating at any time during the study. You may decide not to participate. If so, none of your current benefits or normal health care will be affected in any way. When you feel comfortable that all your questions have been answered, and you wish to take part in this study, sign this form in order to begin your participation. Your signature means you have been told about the study and what the risks are. Your signature on this form also means that you want to take part in this study.

B. Number of Participants

The goal is to have 2,000 people to take part in this study at Mayo Clinic, Rochester. Participation is voluntary. Your decision will not affect your health care at Mayo Clinic in any way.

C. Additional Information You Should Know

Gilead Sciences, Inc. is funding the study. Gilead Sciences, Inc. will pay your study doctor or the institution to cover costs related to running the study.

2. What Will Happen To You While You Are In This Research Study?

If you agree to be in the study, you will be asked to participate in the following:

- Provide a sample of blood: 3 tablespoons will be drawn at Mayo Clinic or during community visits using the Center for Translational Science Activities mobile unit.
- After the initial blood draw, the investigators may wish to obtain up to 5 more additional blood samples per year at about 2-month or greater intervals. These blood samples will be obtained if you return for follow up visits at Mayo Clinic. If possible, the research blood will be drawn at the same time as blood is drawn as part of your regular medical follow up care.
- You will be asked to complete a questionnaire that will ask your health history and your known family history; and will take around 40 minutes to complete.
- Allow us to obtain information from your medical record to gather information needed for the research. Researchers are interested in information in your records about hepatitis B, hepatitis C, or liver cancer. If you agree, you will not be informed when researchers look at your medical records.
- Reportable Disease Testing: If it is not known if you have hepatitis B, hepatitis C you will need to have a blood test done. If your hepatitis B or hepatitis C tests result is positive you will need to have a second test done to make sure the results are the same. The researcher will tell you how to find medical help and counseling as needed. Your health insurer or you will have to pay for the cost of the repeat test, any follow-up medical care, or counseling. If the hepatitis B or hepatitis C test results are positive, it is the state law that they be reported to the State Department of Health. The test results will also be put in your medical record.

3. How Long Will You Be in This Research Study?

You will be in the study for 2 years.

4. Why You Might Want To Take Part in This Research Study

This study will not make your health better. It is for the benefit of research in humans. Particularly, it is important to people of African and Southeast Asian descent as there has never been a comprehensive study on hepatitis B, hepatitis C or liver cancer in African or Southeast Asian community. As mentioned earlier, these infections are known risk factors for liver cancer. Therefore, in case your result is positive, you will be advised to seek further medical attention.

5. What Are the Risks Of This Research Study?

The risks of drawing blood include pain, bruising, or rarely, infection at the site of the needle stick.

Some questions you will be asked to answer in the study questionnaires may make you feel uncomfortable. You may choose not to answer any questions that make you feel uncomfortable.

1) Will women of child-bearing-potential be allowed to participate in this study?

Yes: Women of child-bearing-potential will be able to participate in this study because the risk to an unborn child appears to be very small

2) Will pregnant, and/or nursing women be allowed to participate in this study?

Yes: Women who are pregnant, and/or nursing may take part in this study because the risk to an unborn or nursing child appears very small.

3) Will men who are able to father a child be allowed to participate in this study?

Yes: Men who are able to father a child are allowed to take part in this study.

Risk summary

The risks of this research study are minimal, which means that we do not believe that they will be any different than what you would experience at a routine clinical visit or during your daily life.

6. What Other Choices Do You Have If You Don't Take Part In This Research Study?

This study is only being done to gather information. You may choose not to take part in this study.

7. Are There Reasons You Might Leave This Research Study Early?

Taking part in this research study is voluntary. You may decide to stop at any time. You should tell the researcher if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the researchers, the study sponsor, or Mayo may stop you from taking part in this study at any time:

- if it is in your best clinical interest,
- If the you do not follow the study procedures,
- If the study is stopped.

8. Will You Need To Pay For Any Of The Tests And Procedures?

You will not need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Blood Test

However, you and/or your health plan will need to pay for all other tests and procedures that you would normally have as part of your regular clinical care.

If you have study related questions regarding billing, insurance or reimbursement, stop by: Admission and Business Services office, or call Patient Account Services at (507) 266-5670.

9. Will You Be Paid For Participating In This Research Study?

If you meet the criteria and agree to participate in the study, you will be required to sign a consent form. Before formal enrollment into the study, you will be educated about the nature of the study which may take up to 30 minutes and approximately 40 minutes to fill a questionnaire. Therefore, we are providing a \$20 compensation for your time and inconvenience of participating in this study.

10. What Happens If You Are Injured Or Ill Because You Were In This Research Study?

If you have side effects from taking part in this study, you need to report them to the researcher and your regular physician, and you will be treated as needed. Mayo will give medical services for treatment for any bad side effects from taking part in this study. Such services will be free if not covered by a health plan or insurance. No additional money will be offered.

11. What Are Your Rights If You Are In This Research Study?

Taking part in this research study will not change your rights and benefits. Taking part in this research study does not give you any special privileges. If you decide to not participate in this study, or stop in the middle of the study, no benefits are taken away from you. Specifically, you do not have to be in this research study to receive or continue to receive medical care from Mayo Clinic.

You will be told of important new findings or any changes in the study or procedures that may affect you or your willingness to continue in the study.

12. What About Your Privacy?

Authorization to Use and Disclose Protected Health Information

Your privacy is important to us, and we want to protect it as much as possible. By signing this form, you authorize Mayo Clinic and the investigators to use and disclose any information created or collected in the course of your participation in this research protocol. This information might be in different places, including your original medical record, but we will only disclose information that is related to this research protocol for the purposes listed below.

This information will be given out for the proper monitoring of the study, checking the accuracy of study data, analyzing the study data, and other purposes necessary for the proper conduct and reporting of this study. If some of the information is reported in published medical journals or scientific discussions, it will be done in a way that does not directly identify you.

This information may be given to other researchers in this study, including those at other institutions, or private, state or federal government parties or regulatory authorities in the USA and other countries responsible for overseeing this research. These may include the Food and Drug Administration, the Office for Human Research Protections, or other offices within the Department of Health and Human Services, and the Mayo Clinic Office for Human Research Protections or other Mayo groups involved in protecting research subjects.

Information Disclosed to Study Sponsor

This information may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV). It may also include information relating to behavioral or mental health services or treatment and treatment for substance abuse.

If this information is given out to anyone outside of Mayo, the information may no longer be protected by federal privacy regulations and may be given out by the person or entity that receives the information. However, Mayo will take steps to help other parties understand the need to keep this information confidential.

This authorization lasts forever.

You may stop this authorization at any time by writing to the following address:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

13. What Will Happen to Your Samples?

Part of our samples will be sent to a central laboratory. The central laboratory can use your samples solely for research purposes as described in the research study. Your sample will be returned to Mayo or destroyed upon termination or expiration of the research study. Your sample will be sent to the central laboratory in a coded format, which protects your identity. Mayo has the right to end storage of the sample without telling you.

Part of your sample of blood will be kept at Mayo for use in this study. Researchers at Mayo who are not involved with this study may ask to use your sample for more research. You have a say in how your stored sample is used in future research. You can still take part in the study without giving your sample for future use.

If you agree to allow your sample to be used for further research, the sample may be stored forever. The sample will be stored at Mayo and would be given a code (instead of your name) while it is stored and when it is used in research. This code allows your sample to be used without anyone knowing that it is your sample just by looking at the label.

There is a very small chance that some commercial value may result from the use of your donated sample. If that happens, you will not be offered a share in any profits.

Risks:

Some future studies may be for testing the genes you inherited from your parents (also known as genetic testing). If a researcher finds that future test results may be useful for your health care, you will be contacted and given the choice to learn the test results. At that time, you will be given general information on the potential risks, benefits, and costs of choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or family conflicts from learning unknown information about your parents or blood relatives. Test results will only be put into your medical record if you chose to learn the results. Sometimes results should be released only through a genetic counselor, who can help explain the possible risks and benefits of learning the results.

Exceptions when your samples may be used without your permission:

- 1) When government rules allow your sample to be used without identifying you, even with a code.
- 2) When use of the sample is not considered human subject research.

At all other times:

- You can let Mayo use your sample.
- You can say NO to have your sample used by Mayo.



Please read the following statements and mark your choice:

1. I permit my sample or cell-line to be stored and used in future research of *hepatitis B and hepatitis C* at Mayo:

☐ Yes ☐ No Please initial here: _____ Date: _____

2. I permit my sample to be stored and used in future research at Mayo to learn about, prevent, or treat any other health problems:

☐ Yes ☐ No Please initial here: _____ Date: _____

Who will use your sample?

If you agree to give your sample, it will be the property of Mayo and may be used for research by Dr. Lewis R. Roberts and other staff at Mayo Clinic. Researchers at other institutions may also ask for a part of your sample for future studies.

How do researchers from other institutions get the sample?

Researchers from universities, hospitals, and other health organizations conduct research using tissue. They may contact Mayo and request samples for their studies. If you approve release of your sample by checking 'yes' below, Mayo may send the tissue sample(s) and some information about you to researchers who request them, but Mayo will not send your name, address, phone number, social security number, or any other identifying information with the sample. If you allow your sample to be given to researchers at other institutions, it will be given to them with a code number rather than your name. If these researchers use the sample for future research and decide that a test result may be useful for your health care, they may contact the Mayo Clinic and Mayo would then contact you to offer you the choice to learn the test results. Mayo has the right to end storage of the sample without telling you.

I permit Mayo to give my sample to researchers at other institutions:

Please mark one box:

☐ Yes ☐ No Please initial here: _____ Date: _____

If you want your sample destroyed at any time, write to:

Lewis R Roberts, M.B., Ch.B., Ph.D.
Gastroenterology and Hepatology
Mayo Clinic Rochester
200 First St. S.W.
Rochester, MN 55905
(507) 284-2845



If you move please send your new address to:

Mayo Clinic Rochester
Section of Registration
200 First Street Southwest
Rochester, MN 55905

14. Who Can Answer Your Questions?

You can call ...	At ...	If you have questions or concerns about ...
Principal Investigator: Lewis R Roberts, M.B., Ch.B., Ph.D. Other Study Contact: Essa Mohamed Abdul M. Oseini, M.D. (Mankato) Study Coordinator: Nasra Giama, RN	Phone: (507) 538-4877 Phone: (507) 293-3828 (507) 625-4031 Phone: (507) 538-0097	Questions about the study tests and procedures Study-related questions Research-related injuries or emergencies Any research-related concerns or complaints
Mayo Clinic IRB Research Subject Advocate	Phone: (507) 266-4000 Toll-Free: (866) 273-4681	Rights of a research subject Use of Protected Health Information Any research-related concerns or complaints
Research Billing	Rochester: (507) 266-5670	Billing / Insurance Questions

15. Summary and Enrollment Signatures

You have been asked to take part in a research study, at Mayo Clinic. The information about this study has been provided to you to inform you about this study.

- I have read the whole consent form, and all of my questions have been answered to my satisfaction.
- I am satisfied that I have been given enough information about the purpose, methods, risks, and possible benefits of the study to decide if I want to join.
- I know that joining the study is voluntary and I agree to join the study.
- I know that I can call the investigator and research staff at any time with any questions or to tell them about side effects.
- I know that I may withdraw from the study at any time.
- I will be given a copy of this completed form.

Please sign and date to show that you have read all of the above guidelines. Please do not sign unless you have read this entire consent form. If you do not want to sign, you don't have to, but if you don't you cannot participate in this research study.

(Date / Time)

(Printed Name of Participant)

(Clinic Number)

(Signature of Participant)

(Date / Time)

(Printed Name of Individual Obtaining Consent)

(Signature of Individual Obtaining Consent)