



Title: Role of ROX™ and BOX™ biomarkers as monitors of Interferon Treatment response in Hepatitis C patients.

PI: Zamir S Brelvi MD, PhD

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Role of ROX™ and BOX™ biomarkers as monitors of Interferon Treatment response in Hepatitis C patients

This consent form is part of an informed consent process for a research study and it will give information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand. After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The principal investigator Dr. Zamir Brelvi or another member of the study team. Dr. Dharmesh Kaswala and Dr. Nitin Patel, and Robert Bierwirth, MD (an investigator), will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep. You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

SPONSOR OF THE STUDY:

This study is not a sponsored study.

The study doctor is interested in finding out if you can fully understand the information you are being given. You need to fully understand the information before you can give your informed consent to enter into this research study.

You will be told if your illness has affected your ability to give your consent for this study. If this is the case, the study doctor will talk about whether you should take part in this research study. You have the right to say Yes or No to the study doctors talking to your guardian. You also have the right to say Yes or No to taking part in this research study.

If you agree to enter the study, the study doctor will frequently check whether you are willing to stay in the study until you have completed your part in it.

The study doctor's assessment of your ability to give your informed consent applies only to your volunteering for this research study. It is not an assessment of your ability to make decisions for other purposes, such as making financial, legal, and/or medical decisions.



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Why is this study being done?

This study is being done in order to be helpful in identifying the non-responder for hepatitis C treatment. It may lead to potential cost savings and time savings, for physician patient alike, and may help in preventing side effects from interferon during hepatitis C treatment.

Why have you been asked to take part in this study?

Because you meet the criteria for this study.

Who may take part in this study? And who may not?

Criteria for healthy volunteer subjects: Only those subjects will be included who will not be taking any prescribed medications

Criteria for Hepatitis C subjects:

Inclusion Criteria: Newly diagnosed hepatitis C only subjects.

Exclusion criteria: Immunocompromised, Hypothyroidism, Depression and subjects on Immunosuppressive drugs.

How long will the study take and how many subjects will participate?

Study will take about 12months and total of 40 subjects will participate.

What will you be asked to do if you take part in this research study?

As a Hepatitis C patient, you will be asked to donate 3ml of blood which will be drawn monthly during your regular office visit for standard treatment of Hepatitis C. The 3 ml of blood will be taken at the same time as your normal draw, and no new needle puncture will be necessary.

As a healthy volunteer, you will be donating 3 ml of your blood at the start of the study, and once every 3 months for four times. In summary, the 3 ml blood donations will be for 0, 3, 6, 9, and 12 months for a total of 15 ml of blood for the entire study.

What are the risks and/or discomforts you might experience if you take part in this study?

When your blood is drawn, there may be a bruise, or bleeding, or infection, at the place however, infection is rare.

Are there any benefits for you if you choose to take part in this research study?

The benefits of taking part in this study: for healthy volunteer subjects, will be potential benefits for human beings by this study; for newly diagnosed hepatitis C subjects, will be potential help in identifying the non-responder for hepatitis C treatment. This may lead to potential cost savings and time savings for future patients and physicians, and preventing side effects from interferon during future hepatitis C treatment. However, you might receive no direct benefit from taking part in this study.



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What are your alternatives if you don't want to take part in this study?

Healthy volunteers have the right not to take part in this study. Newly diagnosed hepatitis C patients will still have standard treatment offered even though they do not take part in the study.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to go on taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?

Study is free of cost.

Will you be paid to take part in this study?

No.

How will information about you be kept private or confidential?

All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. All the information regarding the research will be in a password protected computer with password protected Microsoft Office files at Dr. Brelvi's Office and his office will be locked at all times and will require key access to get into.

What will happen if you are injured during this study?

When your blood is drawn, you may have a bruise, bleeding and/or infection at the site. So we will provide you treatment at the site. No additional financial payment to you is available. You are not giving up any of your legal rights by signing this informed consent form or by taking part in this research study.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?

You may choose not to be in the study. If you do choose to take part it is voluntary. You may refuse to take part or may change your mind at any time. If you do not want to enter the study or decide to pull out of the study, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of your data, but you must do this in writing to *Dr. Zamir Brelvi*, UMDNJ-New Jersey Med Sch, 185 S Orange Ave, MSB H-538, Newark, NJ 07103-2714

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.



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Who can you call if you have any questions?

If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

Dr. Zamir Brelvi, MD, Dr. Nitin Patel, MD, Robert Bierwirth, MD, Dr. Dharmesh Kaswala, MD,

GI Department

(973)972-6077

If you have any questions about your rights as a research subject, you can call:

IRB Director

(973)-972-3608 Newark

What are your rights if you decide to take part in this research study?

You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of this study is to identify the patients who have low ROX™ and BOX™ levels. These patients may prove to be the non-responders for interferon treatment. Interferon is a standard treatment for hepatitis C, with the majority of patients being non-responders to interferon treatment. The patients with low ROX™ and BOX™ levels are potential candidates for not responding to interferon treatment. Early identification of non-responders will lead to medical cost savings, will prevent patient suffering from severe side effects from interferon, and will save time and resources for physicians and patients.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study.



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If I sign, can I revoke my authorization or withdraw my information later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows the researchers to continue using and disclosing your information. Therefore, you should be aware that the researchers may continue to use and disclose the health information that was provided before you withdrew your authorization, if necessary to maintain integrity of the research or if the data had already been stripped of all identifiers. If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you may do so in writing by contacting (*Dr. Nitin Patel, MD at 973-972-6077*).

What personal information will be used or disclosed?

Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to all information in a medical record, certain information indicating or relating to a particular medical condition, blood and other tissue samples and related records, physical examinations and radiological examinations.

Who may use or disclose the information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

The UMDNJ-Institutional Review Board

1) Zamir Brelvi, MD 2) Dr. Dharmesh Kaswala, MD 3) Dr. Nitin Patel, MD 4) Dr. Weizheng Wang, MD 6) Dr. Michael Demyen, MD.

Who may receive/use the information?

The parties listed in the preceding paragraph may disclose your health information to the following to persons and organizations for their use in connection with this research study: Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and /or disclosure of your health information will expire:
In 1 year from beginning of research study/approval of study by IRB

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decisions about you and was included in your official medical record.



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AGREEMENT TO PARTICIPATE

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name: _____

Subject Signature: _____ Date: _____

(If Required By The IRB)

Witness Name: _____

Witness Signature: _____ Date: _____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent: _____

Signature: _____ Date: _____

Please initial each one of the following sentences that applies:

_____ I agree to be contacted by the investigators for future research studies.

_____ I do not agree to be contacted by the investigators for future research studies.

_____ I agree to the use of my blood/tissue for future research.

_____ I do not agree to the use of my blood/tissue for future research.

I understand that if I do not want my samples used for future research it will not affect my ability to take part in this study or in future studies.

How will my information be kept private and confidential?

All the information regarding the research will be in password protected computer with password protected Microsoft office-excel and word file at Dr. Brelvi's office.



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My name, date of birth, address, or other personal identifying information, will not be linked with the sample(s) I give. The research is not intended to give me clinical information. I understand and agree that I will not be told about my individual research results. Information resulting from the research will not be entered into my medical records. Neither I, nor my family members, nor outside parties or Investigators will be allowed to look at my individual research results.

It is possible, however, that members of regulatory authorities, such as the U.S. Food and Drug Administration, UMDNJ Institutional Review Board, or other persons required by law may be allowed to look at this information.

What are my rights if I agree to the use of my blood/tissue for other types of research for future research?

I understand that I have the right to ask questions about any part of the future study at any time. I understand that I should not sign this form unless I have had a chance to ask questions and have been given answers to all of my questions.

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed.

All of my questions about this form or this study have been answered.

I agree to the use of my blood/tissue for other types of research.

Subject Name: _____

Subject Signature: _____ Date: _____