Central Virginia Veterans Affairs Health Care System (CVHCS)
McGuire Institutional Review Board
Consent Form

Template Version Date: (6/15/2021)

Title of Research Study: Characterization of Venous Ammonia Levels in Fasted and Fed State in Patients with Cirrhosis after Vegetarian, Vegan, and Non-Vegetarian Meals

Sponsor: Investigator Initiated

Protocol Number: BAJAJ 0030

Investigator Name & Address: Jasmohan Bajaj, MD; Department of GI/Hepatology; 1201 Broad Rock Boulevard (111N); Richmond VA 23249

KEY INFORMATION:

We are asking you to consider participation in this research study which will compare the effects of vegan, vegetarian, and non-vegetarian meals on different laboratory values in the blood and stool of patients who have been diagnosed with cirrhosis (scarring of the liver). This initial information is provided to help you decide whether or not to participate in the study.

Your participation in this study will include one study clinic visit which will last approximately 4 hours and will include consuming a specific meal and the collection of blood, stool and urine samples.

You may want to participate in this study because the information gained from this research study may help people with cirrhosis in the future. You may not want to participate because of the time involved in participating in the study. You may choose not to enroll in the study and continue receiving routine care for your liver disease.

Additional detailed information is provided for your review in the sections below. Ask the research team questions until you feel you have enough information to make your decision about whether to participate. Participating in this research study is completely voluntary. Your decision to participate or not will have no effect on any of the services, benefits or rights to which you are otherwise entitled.

The person in charge of this study is Dr. Jasmohan Bajaj and he can be reached at (804) 675-5021. Other important contact information is listed below.

1. Whom should I contact for questions?
If you have any questions, concerns or complaints regarding this study, unexpected reactions, or you are injured and become ill as a result of participation in this study please call AM or PM*:*

	Office	**Off Hours**
Dr. Bajaj	**(804) 675-5021**	**(804) 675-5021**
Research Coordinator	**(804) 675-5584 or (804) 675-2991**	

If you are unable to reach any of the study staff listed and need immediate medical assistance, please call the McGuire VA Medical Center operator at **(800) 784-8381** and ask for the Emergency Room physician to obtain advice or call the **Emergency Room directly at (804) 675-5527**. If you have any questions, concerns or complaints about your rights as a research subject you may contact the **McGuire Institutional Review Board (IRB) at (804) 675-5676.** The IRB is responsible for reviewing research in humans and making sure that their safety and rights are protected.

2. **What is this research study about?**
You are being asked to participate in this research study because you have been diagnosed with cirrhosis. When the liver is damaged, it does not remove toxins (damaging substances) from the blood as well as a non-damaged liver would, and these toxins can build up and cause mental and physical symptoms. One of these toxins is ammonia. One of the goals of this study is learn more about the effects of different foods on ammonia levels and to apply this knowledge to help treat or prevent the complications of increased ammonia levels in people with cirrhosis.

In this study, you will be assigned randomly (by chance, like the flip of a coin) to receive one of three different meals:

- Vegan: bean burger, chips, water
- Vegetarian: meat substitute burger, chips, water
- Non-Vegetarian: beef burger, chips, water

Up to 60 subjects will participate in this study here at McGuire VA Medical Center. Your participation will include a single study clinic visit.

3. What is expected of me?
If you agree to participate, you will be asked to sign this consent form before any study procedures are done. The tests and procedures described below are being done for the purposes of this research.

You will be asked to fast, which means nothing to eat or drink (except water) for at least 4 hours before your study clinic visit.

Study Clinic Visit

- You will be asked about your current health, and your past medical and surgical history.
- You will be asked about any medications (prescription or over the counter), vitamins, supplements or natural remedies you are currently taking.
- A physical exam will be done.
- Your weight will be measured.
- Your vital signs (heart rate, blood pressure) will be measured before your meal and before you are discharged from study clinic.
- Blood samples will be collected for testing five times: at baseline, before your meal and then again at 1, 2 and 3 hours after your meal.
- Urine will be collected for testing two times during your study clinic visit.
- You will be given a kit to collect a stool sample. The study staff will provide further instructions about its use.
- You will be asked to recall all food and drink that you have consumed over the last 3 days.
- You will consume your assigned meal, and you will be observed in the study clinic for a total of 3 hours following your meal.

4. **Will my data and/or samples be kept for use in the future?**

After the removal of identifiable information, the information and/or samples collected from you as part of this research may be used for future research studies without additional consent from you.

Blood, Urine and Stool Samples

- Your samples will be labeled with a code, and the label will not include any information that directly identifies you, like your name or birthdate.
- At any time, you may request in writing to Dr. Bajaj that all samples be destroyed to prevent future testing. However, information that has already been gathered cannot be destroyed.

***Optional* Future Research**

Choosing to participate in this part of the study is optional, and you can still be in the main study if you choose not to participate.

Your samples will be stored in a research laboratory at McGuire VA Medical Center and may be shipped to one or more laboratories for testing. Your samples will be labeled with a code and the label will not include any personally identifying information.

I agree to allow Dr. Bajaj to keep a portion of my blood, urine and stool specimens collected during the study for future scientific research.

YES ☐ ___Initials

NO ☐ ___Initials

5. Will the research benefit me?
You will not receive any benefit from participating in this study. Your participation could help people with liver disease in the future.

6. What are my alternatives to being a research subject?
You will not receive treatment for your medical condition in this study. Your alternative is not to participate.

7. What are my risks?
Participation in this study may involve risks that are unknown at this time. You should let the study staff know about any changes in your health or any symptoms, side effects, complaints, illnesses or injuries you may have while you are participating in this study.

Each of the three different meals will be prepared and administered under the guidance of a study dietician. You will be observed in the study clinic for 3 hours following your meal.

Blood Draws
The risks of blood drawing include pain, bleeding, bruising, and very rarely, an infection at the site of the blood draw. Some people may experience dizziness, nausea or fainting when they have blood drawn.

8. Will I get paid?
You will be paid $125 after the completion of all study related testing.

If you receive payments from McGuire Research Institute greater than $600 in a calendar year, they will be reported to the IRS along with your social security number.

9. Will I have to pay?
You will not have to pay, and your insurance will not be billed for treatments or procedures that are part of this study regardless of whether you are a Veteran or a non-Veteran. If you get a bill for research services, contact the study staff. Some Veterans are required to pay co-payments for medical care and services provided by CVHCS.

These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of the study.

10. Does pregnancy prevent me from participating?
Every effort will be made to have females enter this study, and pregnancy does not prevent you from participating in this study.

11. What if I get injured?
A research injury is any injury or illness caused by participation in a research study. In the event of a research injury caused by participation in this study, necessary medical treatment will be provided at no cost to you, whether you are a Veteran or a non-Veteran. This care may be provided by CVHCS or arrangements may be made for care at another facility.

If you believe you have an injury resulting from your participation in this research study, you should contact your study team. If you want to speak to someone who is not a member of the study team to discuss problems, ask questions or voice concerns, you may call the McGuire IRB at (804) 675-5676.

This agreement does not include treatment for injury or illness that is not a result of the study. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form, and you are not releasing this institution from liability.

12. Who Will See My Information?
The study team will put information about your participation in this study in your medical record. The confidentiality of your research records will be maintained according to professional standards of confidentiality and Veterans Health Administration (VHA) regulations. Records identifying you may be reviewed by the members of the research team, the Research and Development Committee and its sub-committees, accrediting agencies, officials from the VHA, the Office of Research Oversight, the VA Office of the Inspector General, CVHCS, McGuire Research Institute and its auditor, and other federal oversight agencies such as the FDA, Office for Human Research Protections, or as required by law.

All information collected about you while you are in the study, including your name, birthdate and social security number will be protected. Study records will be kept in locked filing cabinets and on computers protected with passwords.

During the study, the results of some testing done for research purposes may not be made available to the study staff or you, and will not be placed in your medical record.

The study doctor will share any clinically relevant results with you. You will not have access to your research-related health records while you are participating in this study.

The ways your study doctor will use your study-related health information and the people who may receive it are identified in a separate form entitled “Authorization for Use and Release of Individually Identifiable Health Information for VHA Research”. You will be asked to sign that form to show that you give permission for these uses and sharing of your information. You do not have to sign the authorization form, but if you do not sign, you may not participate in the study.

If you are a non-Veteran receiving care as part of this study, you will have an electronic CVHCS medical record created for you. You will also be given a VA Notice of Privacy Practices.

13. Do I have to participate in this study, or can I withdraw from the study?
Participation in this study is voluntary and you may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. The study staff will answer any questions you may have about the study. You are free to withdraw your consent and stop participation at any time. If you decide to withdraw from this study, you should contact Dr. Bajaj to discuss termination of your participation. Stopping will in no way change the quality of care you receive now or in the future at this institution or your right to participate in other studies.

If you choose to withdraw, you may request that your samples are destroyed and no further testing is done.

Any significant new findings that develop during the research study that may affect your decision to continue participating will be provided to you as soon as possible.

Your participation in this research study may be ended without your consent for the following reasons:

- If the study doctor believes, for any reason, that it is within your best interest
- If you develop side effects that are considered dangerous
- If you fail to follow the study doctor’s instructions
- If other causes prevent continuation of the clinical research study.
- Dr. Bajaj or the McGuire IRB may end the study at any time.

14. Date of Consent Form Revision: October 28, 2021

Subject Name:_____ **Date:**_____

Title of Research Study: Characterization of Venous Ammonia Levels in Fasted and Fed State in Patients with Cirrhosis after Vegetarian, Vegan, and Non-Vegetarian Meals

Principal Investigator*:* Jasmohan Bajaj, MD **CVHCS:** Richmond

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above.

Dr. **Bajaj** (or an associate) has explained the study to me and answered all my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled. The results of this study may be published, but my records will not be revealed unless required by law.

By signing below, I am agreeing to participate in this research study. I will receive a signed copy of this consent form.

_____ _____

Subject's Signature **Date**

_____ _____

Signature of Person Obtaining Informed Consent **Print Name** **Date**