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

Template Version Date: (6/15/2021)

Title of Research Study: Application of Dieta App to Study Stool Characteristics and BiomeSense to Collect Stool for Microbiota in Patients with Cirrhosis and Hepatic Encephalopathy

Sponsor: Investigator Initiated

Protocol Number: BAJAJ 0033

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 be looking at the use and accuracy of a mobile application called the Dieta app in assessing stool characteristics in subjects with cirrhosis (scarring of the liver) and in healthy volunteers. The app's ability to assess stool characteristics will be compared to the subjects' description of the stool. Laboratory testing will be done to assess the composition of bacteria and other microbes (microorganisms that are too small to see with the naked eye) in the stool. This initial information is provided to help you decide whether to participate in the study.

Your participation in this study will include one study clinic visit which will last approximately 1 hour. You will be asked questions about your health, your diet and any medications you are taking, and a stool sample will be collected. You will be trained on the app and will be asked to photograph each bowel movement and record information about bowel movements and your medications for a 2-week period. Study staff will phone you twice during this time to see if you have any questions or are having any issues with using the app. After you complete the study, you will receive a phone call to find out about your experience using the app.

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, if applicable.

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) 675-5802**	**(804) 675-5021**
Research Coordinator	**(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 Department physician to obtain advice or call the **Emergency Department 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 either because you have been diagnosed with cirrhosis or you are being asked to participate as a healthy volunteer. One of the goals of this study is learn more about the ability of the Dieta mobile application to accurately characterize the appearance and other characteristics of stool (such as number, volume, consistency). Researchers also will be documenting the ease or difficulty of using this app and whether this app is useful in tracking stool characteristics and other factors such as diet, medication intake, and any symptoms you may be experiencing.

The study will require that you have a smartphone and that you download and activate the Dieta app. Study staff will instruct you on the use of the app. Following study

completion, you will be asked to delete the app from your device as the study team will no longer be monitoring its use.

Up to 60 subjects will participate in this study here at McGuire VA Medical Center.

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.

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.
- You will be asked to complete a questionnaire about your health and general quality of life. This may take about 20 minutes to complete.
- You will be asked to complete a questionnaire regarding your thoughts and opinions about using the Dieta app before you start the study. This may take about 10 minutes to complete.
- A stool sample will be collected for testing or you will be given a kit to collect a stool sample at home. The study staff will provide further instructions about this.
- You will be asked to recall all food and drink that you have consumed over the last 24 hours.
- Study staff will train you on the use of the app and make sure you feel comfortable using it to record your medication(s), diet, and any symptoms you may be experiencing. They will review the use of a picture tool called the Bristol Stool Scale and how you will record the appearance of your bowel movements.

Using the App: Two Weeks After Study Clinic Visit

- You will be asked to take a photo on your phone of each bowel movement.
- You will be asked to document the appearance of each stool using the Bristol Stool Scale.
- You will be asked to document medications, diet, and any symptoms you are having.
- Study staff will call you twice during this 2-week period to see if you are having any difficulty using the app, and they will provide additional training if needed. The exact length of each phone call will depend on whether you have questions for the study staff or need additional assistance in using the app.

Follow-Up Phone Call

- The study staff will contact you by phone to complete a questionnaire regarding your thoughts and opinions about using the Dieta app.

***Optional* BiomeSense (GutLab™) Sample Collection (Cirrhosis Group Only)**
Participating in this portion of the study is optional. You may participate in the main study even if you choose not to participate in this sub-study.

If you choose to participate, you will be asked to collect a sample of stool daily for 2 weeks by placing a piece of used toilet paper containing stool into a collection device after each bowel movement. The collection device, which is about the size of a desk-top computer, will be temporarily installed near your toilet at home. The study team will arrange a time to deliver and install the device, and they will provide you with detailed instructions about using it.

At the end of the 2-week collection period, the study team will remove the device from your home. If you decide you do not wish to continue participating in the study, the study team can arrange to have the device removed from your home before the 2-week period is ended.

The study team will ask you questions about your experience using the stool collection device. This may be done in person or by phone, and should take less than 5 minutes.

I agree to participate in the Optional BiomeSense/GutLab™ stool collection portion of the study.

YES ☐ ___Initials

NO ☐ ___Initials

4. **Will my data and/or samples be kept for use in the future?**
The information and/or samples collected from you as part of this research, even if identifiers are removed, will not be used or distributed for future research studies unless you choose to participate in the "***Optional* Future Research**" portion of the study described below.

Stool Sample
- Your sample 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 will not be destroyed.

***Optional* Future Research**

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

If you choose to participate in the Optional Future Research part of the study, your stool sample will be stored indefinitely in a research laboratory at McGuire VA Medical Center and may be shipped to one or more laboratories for testing.

I agree to allow Dr. Bajaj to keep a portion of the stool specimen collected during the study for future 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 benefit people in the future who have liver disease and other conditions.

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

7. What are my risks?
No risks are anticipated from your participation in this study. However, participation in this study may involve risks that are unknown at this time.

8. Will I get paid?
You will be paid $100 for each completed week of mobile app use.

You will be paid an additional $100 per week for completed sample collection if you choose to participate in the Optional Biomesense GutLab Sample Collection portion of the study.

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. Information presented or published about the results of this study will not identify you.

During the study, the results of testing done for research purposes will not be placed in your medical record. 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.

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 other causes prevent continuation of the research study.
- Dr. Bajaj or the McGuire IRB may end the study at any time.

14. Date of Consent Form Revision: September 16, 2022; February 13, 2023

Subject Name:_____ **Date:**_____

Title of Research Study: Application of Dieta App to Study Stool Characteristics in Patients with Cirrhosis and Hepatic Encephalopathy

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

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all 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**