

Medically-Tailored Meals to Prevent Recurrent
Hepatic Encephalopathy: The BRAINFOOD Pilot
Trial

Date of IRB Approval: May 21, 2021

NCT04675775

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Medically-Tailored Meals to Prevent Recurrent Hepatic Encephalopathy: The BRAINFOOD Pilot Trial (Stage 2)

Company or agency sponsoring the study: There is no sponsor.

Principal Investigator: Elliot Tapper, MD, University of Michigan, Department of Internal Medicine, Division of Gastroenterology

Study Coordinator: Samantha Nikirk, MPH, University of Michigan, Department of Internal Medicine, Division of Gastroenterology

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This is a research study for patients with cirrhosis, including patients with a prior history of hepatic encephalopathy (HE,) to evaluate the benefits of medically-tailored meals as an intervention. Up to 20 eligible patients will be enrolled from the University of Michigan, with the goal being for all patients to complete the baseline assessments in-person, (4) 24-hour diet recalls, 6 weeks of medically-tailored meals, 1 in-person follow-up study visit where follow-up assessments will be conducted, and a follow-up phone visit where you will complete some of the baseline assessments again and complete a semi-structured exit interview.

This research study collects health-related information to better understand the ability to carry out a larger trial that uses medically-tailored meals in this patient population. We will collect data that will

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help researchers to understand patients' compliance with study-related activities, specifically the medically-tailored meals, improvements in nutritional intake provided by the meals, and any other improvements in health, quality of life, or cognitive function as a result of the provided meals. The results of this study will not only include the data obtained from the administered assessments, but researchers will also be tracking enrollment success, telephone follow-up success, and time taken to complete assessment. Additionally, the semi-structured interview to be conducted at the conclusion of the study will provide data on patients' likes and dislikes as they relate to the provided meals and the study design as a whole. Results of this pilot study will be used to help researchers to understand the ability for medically-tailored meals to be used as intervention for HE.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include risk of breach of confidentiality, lack of improvement of your current cirrhosis complications and quality of life, psychological discomfort due to the questionnaires, physical discomfort, tiredness, or pain as a result of the physical assessments, and new symptoms from the prescribed meals. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by improving your health-related quality of life and/or reducing your risk of HE. This study may not offer any benefit to you now but may benefit others in the future by providing more information on the ability of medically-tailored meals to be used to prevent recurrent HE. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be approximately 21 weeks (about 5 $\frac{1}{4}$ months). However, your participation could last up to 27 weeks (about 6 $\frac{3}{4}$ months).

You can decide not to be in this study. Alternatives to joining this study include standard of care monitoring and procedures as recommended by your liver doctor.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Studies have shown that over 40% of patients with cirrhosis develop HE, which is associated with higher death rates, malnutrition, loss of muscle tissue, weakness, falls, and frequent hospitalizations. HE is caused by high levels of ammonia in the brain, which can be combatted with a high protein diet. Research has shown that medically-tailored meals are cost-effective and can reduce the risk of readmissions. We do not know, however, if home-delivered high protein meals can reduce the risk of HE in patients with a recent episode. This research study is being done to learn what effect medically-tailored meals will have in patients with a recent history of HE.

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3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Any adult (18+) who has been determined by the liver team doctors as having cirrhosis, a history of hepatic encephalopathy, or a history of ascites.

If you currently have a history of a liver transplant, have a history of an eating disorder, are pregnant, or are physically or mentally incapable of completing the assessments, you are not eligible to participate in this study.

3.2 How many people are expected to take part in this study?

At least 20 subjects with a history of hepatic encephalopathy are expected to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to take part in this study, you must read and sign this consent form before any study-related tests or procedures are performed.

Screening visit

During the screening visit, which happens in-person either before/after a previously scheduled clinic appointment, a procedure visit, an inpatient stay, or via phone, you will be asked questions about your health to see if you are eligible to participate in the study. If you can still be in the study, we will continue with surveys about your demographics and health history. Medical information will be extracted from medical records and verified at the time of your baseline visit. Our review looks at your liver-related clinic notes, labs, and imaging in order to document the cause of your cirrhosis, history of liver cancer, history of cirrhosis complications, and medication history.

For this visit, we will collect the following information on you either from your medical record or directly from you:

- Demographics – sex, age, race/ethnicity, occupation, income and education
- Review your medical history, medications, history of falls, and alcohol history

Run-in Phase

Following enrollment, you will participate in a 4-week run-in phase where researchers will observe you to evaluate your interest in this study. During this period, you will undergo (2) 24-hour diet recalls that will be carried out by a registered dietitian from the University of Michigan Nutrition Obesity Research Center who will contact you by phone.

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Baseline Visit

At the end of this run-in period (approximately 4 weeks after enrollment), you will be asked to complete a baseline visit either in person at the University of Michigan or via phone.

During this visit, you will:

- Perform hand-grip strength tests (1 minute) – you will demonstrate the strength of your grip using your dominant hand 3 times (not done if via phone)
- Perform 5 Chair Stands – the amount of time you take to complete 5 rises from a seated position (not done if via phone)
- Perform a walk speed test – the amount of time you take to walk 10m (not done if via phone)
- Perform a balance test – the amount of time that you can hold 3 balancing positions (not done if via phone)
- Complete several questionnaires by pen on paper (20-25 minutes). The surveys will ask you questions related to your quality of life, quality of sleep, ability to work and care for yourself, and support system.
- Complete two tests designed to assess the impact of your liver problem on how you feel. The first is a brief test that measures how fast you can do a simple task (1 minute) and the second is a computer program that will be presented to you on an iPad and will test your concentration by having you follow instructions and measuring your response (10-15 minutes) (the test on the iPad will not be performed if the visit is done via phone)
- You will also be asked to complete a dietary assessment via a software called Vioscreen, using your personal laptop, tablet, or smartphone from home. This assessment will take about 30 minutes and the software will ask you questions about the foods and drinks that you have on a regular basis in order to give researchers more information about your regular diet.

We will measure the time that it takes for you to complete the above assessments.

You will also receive a standardized nutrition education handout with instructions on following a high-protein+sodium restricted diet and be enrolled in medically-tailored meals prepared by Purfoods, LLC. PurFoods specializes in providing home-delivered, specialized dietitian-curated meals to patients with various medical conditions such as liver disease, chronic kidney disease, cancer and cardiovascular disease. Additional information about the company and their services can be found here:

<https://www.momsmeals.com/>. You will receive meals that adhere to specified nutritional targets dependent upon your cirrhosis complications. Study food will be pre-packaged for storage with preparation (typically microwave heating) to be completed at home.

Your home-delivered meals will be ordered at this time and you will be provided with protein supplements (protein bars and protein powder/liquid protein) either in person or via home delivery to be taken during the interventional phase. For a daytime protein supplement, you will be provided a protein bar by the study coordinator. The protein bar will be from the companies ZonePerfect and The

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Perfect Bar. For your nighttime protein supplement, the study coordinator will provide you with one of the following two options. The first option is a protein powder that can be dissolved in either water or milk. We will provide you with ProCel Chocolate Whey Protein powder. The second option is a liquid protein option that can be mixed with a cup of water. We will provide you with LiquaCel packets of liquid protein.

Interventional Phase

You will receive the meals at home within 3-5 days and should begin eating the meals and taking the protein supplements the day after they arrive at your home. You will be expected to consume the meals and protein supplements for a total of 6 weeks (42 days).

During this 6 weeks, you will undergo (2) 24-hour diet recalls via phone on two separate occasions. Once per week you will receive a phone call from a study team member where you will be able to ask any questions and express any concerns about the diet or the study in general.

Follow-up #1

Approximately 9 weeks after your enrollment in this research study, but no more than 13 weeks afterwards, you will be asked to complete a second study visit wither via phone or in person at the University of Michigan. At this visit, all baseline assessments will be repeated in the same order unless done via phone. These assessments will include:

1. Quality of Life Questionnaire
2. Self-efficacy Questionnaire
3. EncephalApp Stroop Test (not done via phone)
4. Walk Speed Test (not done via phone)
5. Balance Test (not done via phone)
6. Hand Grip Test (not done via phone)
7. Animal Naming Test
8. Support System Questionnaire
9. VioScreen FFQ (can be done from home)

Observation Phase

Following the first in-person follow-up visit, you will be observed for an additional 12 weeks from this date. During this observational phase, you will be contacted every two weeks via phone and/or email in order to maintain contact.

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Follow-up #2

The 12-week observational period will be concluded with a phone assessment where you will talk with a member of the research team about your likes and dislikes of the study, your satisfaction of the medically-tailored meals, and your use of the healthcare system.

Study Activities

Entry/ Day 1*		RUN-IN → BASELINE		INTERVENTION		FU 1	OBSERVATI ON	FU 2
		STUDY DAYS						
		11 (±8 days)	28 (± 7 days)	32 (± 8 days)	67 (± 7 days)	74 (± 8 days)	81 (± 15 days)	81 (± 15 days) → 165 (± 15 days)
Informed Consent	X							
Demographics Questionnaire	X							
SF-8			X			X		X
PROMIS Self-Efficacy			X			X		
EncephalApp			X			X		
Liver Frailty Index			X			X		
Animal Naming Test			X			X		X
PROMIS Instrumental Support			X			X		
Health History Questionnaire	X							
24-hr Diet Recall		2X			2X			
VioScreen FFQ			X			X		
Phone Call/Interview				6x			6x	X
Medically Tailored Meals				X → X				
Healthcare Utilization	CHART REVIEW →							X

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As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, consume the medically-tailored meals as directed, and report any adverse reactions you may have during the study.

4.2 How much of my time will be needed to take part in this study?

Your participation in this study may last up to 27 weeks (about 6 $\frac{3}{4}$ months).

- The enrollment visit will be completed either in-person or via phone and is expected to take about 20 minutes.
- The baseline visit will be completed in-person or over the phone is expected to take about 1 hour.
- The follow-up diet recall(s) will be completed approximately 2 times during the run-in phase (weeks 1-2) and 2 times during the interventional phase (weeks 4-11) and are expected to take about 20 minutes each.
- The second study visit will be completed approximately 9 to 13 weeks after enrollment and is expected to take about 1 hour, either in person or over the phone.
- The follow-up phone call will be completed approximately 21 weeks after enrollment and is expected to take about 30 minutes.

4.3 When will my participation in the study be over?

Your participation in this study will end when you have completed all study related activities or if you fail to complete the baseline appointment in-person, undergo liver transplantation, or decide to leave the study.

4.4 What will happen with my information and/or biospecimens used in this study?

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Questionnaires: Many of the questions relate to how you are feeling, and this may lead to an emotional reaction. To minimize these risks, questions will not ask explicitly sensitive information and study coordinators will be available for support. Additionally, should the questionnaires or surveys become uncomfortable, you can choose to skip any question that you do not wish to answer or stop at any time.

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Loss of confidentiality: There is rare risk of loss of confidentiality or privacy. To reduce the risk of loss of confidentiality, trained members of the research team will ask you questions in a private patient room. Researchers will only provide (to the professionals trained in diet recall) the minimal amount of identifying information necessary in order to complete the diet recall. This information will be limited to your name, date of birth, sex, and subject ID. Your name will only be used during the phone call and will not be reported with the diet recall data.

Information such as your full name and phone number will be recorded along with your baseline data however, this information will be stored in a locked cabinet. This data will be entered into a password-protected database where all data will be coded using a study number and only staff involved in this research will have access to the data. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

Physical Assessments: As a part of the baseline assessments, we will conduct a series of physical assessments. Assessments such as the chair stand test, 10-meter (33 feet) walk, and balance test may result in tiredness, dizziness upon standing, falling, pain, or injury. Though these risks are considered to be relatively minimal, to minimize these risks, study coordinators will be available for support should you experience discomfort and you can choose to stop these tasks at any time. You will be instructed to go as slowly as you feel comfortable and study coordinators will stand nearby and stop the test if you ever feel or appear to be uncomfortable.

Medically Tailored Meals: As a part of the interventional phase, you will be expected to eat the provided medically-tailored meals and protein supplements (protein bars and protein powder/liquid protein) for a total of two weeks. Though it is not likely, there is the possibility of these foods causing unexpected allergic reactions or symptoms such as abdominal pain, diarrhea, nausea, or vomiting. The researchers will try to minimize these risks by providing you with a menu of different meals that you can choose from, along with a list of ingredients contained in each meal.

Additionally, PurFoods provides meal delivery to your home address. The researchers cannot be held responsible for meals that are not delivered for any reason. The researchers will try to minimize these risks by asking you for detailed instructions for delivery to your home.

As with any research study, there may be additional risks that are unknown or unexpected however, we have done everything in our power to foresee and minimize these risks.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

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5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, you will receive a reliable high-protein (and low sodium if you have ascites) diet for a total of 6 weeks and as such, you may experience improvement in your ascites or HE. Either way, the results of this study will improve our understanding of medically tailored meals in patients with HE and may benefit future patients.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Declining to participate in the study will have no effect on the medical treatment you will receive at Michigan Medicine.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No, there will not be any harm to you if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study.

Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

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8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will receive a \$200 payment at the end of this study.

8.3 Who could profit or financially benefit from the study results?

Neither the University of Michigan nor the investigators will profit from the study results.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

No one other than the research team at the University of Michigan and the University of Michigan staff members completing the 24-hour diet recall will be given or have access to your name, address, hospital registration number, and other personal identifying information. Staff members completing the 24-hour diet recall will only have access to your name, phone number, date of birth, and sex. Your name will only be used during the phone call and will be stored separately from the diet recall data. Logs

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containing identifiable information will be stored in locked cabinets or password-protected computers. You will be assigned a unique study number, such as a series of numbers, series of letters or a combination of the two. This number will be the only identifier used in the password-protected database program.

All information collected about you will first be recorded in datasheets and then entered into a password protected database. No identifiable information (for example, your name and hospital registration number) will be entered into the database. Datasheets will be stored in a locked cabinet in the research team's office.

A description of this clinical trial will be available on <http://www.clinicaltrials.gov/>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Alcohol/substance abuse treatment records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
 - Make sure the study is done safely and properly
 - Learn more about side effects
 - Analyze the results of the study

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- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at <http://www.uofmhealth.org/patient+and+visitor+guide/hipaa>. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

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Instructions revised 4-11-2020
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- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Elliot B. Tapper, MD
Mailing Address: 3912 Taubman, SPC 5362
1500 E Medical Center Dr.
Ann Arbor, MI 48109
Telephone: (734) 647-9252

Study Coordinator: Samantha Nikirk, MPH
3912 Taubman, SPC 5362
1500 E Medical Center Dr.
Ann Arbor, MI 48109
Telephone: (734) 232-4182

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate [calling codes](#).)
Fax: 734-763-1234
e-mail: irbmmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (Note: *In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.*)

12. SIGNATURES

Sig-A

Consent/Accent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

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