UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: Creating a Patient Symptom and Food Consumption Reporting Mobile Application

1.2 Company or agency sponsoring the study: Nestle Clinic Nutrition

1.3 Names, degrees, and affiliations of the researchers conducting the study:

William D. Chey, MD, FACG, AGAF, FACP, RFF
Timothy T. Nostrant Collegiate Professor of GI & Nutrition Sciences
Director – GI Physiology Laboratory
Director – Digestive Disorders Nutrition & Lifestyle Program
Medical Director – Michigan Bowel Control Program
Division of Gastroenterology
University of Michigan Health System

Shanti Lynne Eswaran, MD
Assistant Professor
Gastroenterology, Internal Medicine

The University of Michigan will be conducting this research study in partnership with Cedars-Sinai Medical Center (Cedars), located in Los Angeles, CA.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: The "My Nutritional Health" (MNH) smart phone app is expected to provide a unique tool to consumers interested in tracking their food intake and linking diet to GI symptoms. MNH is being developed by Cedar. Data collected from subjects in this study will help us to check the ability of this app to track food intake and correlate diet with specific symptoms across time in a valid and reliable manner. We will be proving the accuracy of our Food and Symptom Tracker (FAST)score for use in the MNH app. FAST score will be used to measure cumulative symptom burden over time. The FAST score is a number that rates the level of severity of the GI reported symptoms and enables to track these symptom changes over time.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

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?
To be eligible for this study, patients must meet the following inclusion criteria:

- Be ≥18 years of age
- Have a scheduled, upcoming new patient visit with a GI dietician at the University of Michigan
- Have access to modern device supporting iOS (tablets, iPads, iPhones, and Android) and internet access, to download and use MNH app.
- Should not be pregnant or not plan on becoming pregnant during study
- Must read and understand English, as the MNH App is available only in English

3.2 How many people (subjects) are expected to take part in this study?
We hope to enroll at least 75 subjects from the University of Michigan in this study. Cedars-Sinai will be enrolling at least 25 subjects in the study. There will be a total of at least 100 subjects taking part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
You will be asked to download the My Nutritional Health App onto your personal smartphone. Once you install the app, you will be asked to enter information about your dietary intakes (meals) and GI symptoms daily, for seven (7) days prior to your visit with your dietitian and for seven (7) days after your visit to your dietitian.

Dietary Intake
You will be asked to report the times of day that you usually eat; this will allow the app to prompt you to enter food and symptom information at appropriate times. You will be asked information regarding the content, size, and timing of the meals that you consumed during each day for a total period of two weeks.

GI Symptom Information
After you report your dietary intake, you will be asked questions about symptoms you have experienced over the last several hours. These symptoms primarily include GI symptoms, but also non-GI meal-related symptoms including fatigue, difficulty with concentration, and headaches.

Additional Questionnaires
Before your appointment with your dietitian, you will be asked to will answer questions on two short questionnaires. These questionnaires will ask questions about the GI symptoms you have experienced over a period of one week. As well as questions that measure any changes to your overall health status. We will also ask you to complete the questionnaire regarding your overall health status again at the end of the second week of assessment.

4.2 How much of my time will be needed to take part in this study?
This study does not involve any visits to the University of Michigan outside of your scheduled dietitian visit. You will use your personal smartphone for all of your study related activities outside of your dietitian visit. You will need to enter all of your dietary intake, daily, for a total of 14 days as well as your daily GI symptoms The amount of time for each entry will be based on your individual dietary habits, but should not take more than 10 minutes for each entry.

4.3 When will my participation in the study be over?
Your participation in this study will end approximately 7 days after your initial visit with the GI dietitian.

4.4 What will happen with my information and/or biospecimens used in this study?
Your biospecimens and collected information may be shared with Nestle Clinical Nutrition.
With appropriate permissions, your samples and collected information may also be shared with other researchers, here, around the world, and with companies.
Your identifiable private information or identifiable biospecimens 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 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 in this study are minimal. You may be uncomfortable answering questions about our diet or symptoms, or uncomfortable answering the questionnaires regarding your overall health status.

The researchers will try to minimize these risks by allowing you to end your participation in this study at any time, for any reason.

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**.**

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.

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. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?
There may be other ways to keep track of your dietary intake or symptoms. These may be discussed with your dietitian at your initial visit.

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" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
You can leave the study anytime at your convenience with no penalty.

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.

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 researchers' 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 $40 for entering your dietary intake, symptoms and completing 2 questionnaires in the 7 days **prior to** your initial visit with your GI dietitian. You will receive $60 for entering your dietary intake, symptoms and completing 1 questionnaire in the 7 days **after your** initial visit with your GI dietitian.

8.3 Who could profit or financially benefit from the study results?
Nestle Clinical Nutrition, the company whose product is being studied, Dr. William Chey, the researchers conducting the study and The University of Michigan could benefit intellectually and financially from the results of this study. 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 your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

Private or personal information about you will be collected during the screening and enrollment process of this research study. This information will be only be seen by approved research staff, and will be stored on protected and encrypted servers and documents.

If you choose to enroll in this study, your private or personal information collected as a part of this research will be stored and protected on a secured cloud based server which conforms to the U.S. Health Insurance Portability and Accountability Act (HIPAA) security

Only staff that have been approved by the University of Michigan Institutional Review board will be able to access, collect and view your private or personal information.

9.2 What information 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. Information 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.)
- HIV/AIDS status
- Sexually transmitted disease or other communicable disease status
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal information

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
- 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?

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 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).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- 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:
William Chey, MD
1500 E Medical Center Dr, 3912 TC
Ann Arbor, MI 48109
Telephone: 734-936-4775

Study Coordinator:
Kenya Jackson
1500 E Medical Center Dr, 3912 TC
Ann Arbor, MI 48109
Telephone: 734-764-9226

You may also express a 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: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@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 electronic assent means that you have received an electronic copy 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. ASSURANCES

REQUIRED ASSURANCES: <Any negative responses, except for the request for a printed version of this content will stop enrollment on the study.>

Before you can continue, we need your answers to these questions:

I am age 18 or older.

☐ Yes ☐ No

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with a member of the research team. 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).

☐ Yes ☐ No

I consent to participate in this research and continue with the survey. I understand that if my ability to consent changes, I may be asked to re-consent prior to my continued participation in this study

☐ Yes ☐ No

I have read and understand that I am granting permission for the research team to collect health information (Dietary intake, GI symptoms, and overall health status) about me.

☐ Yes ☐ No

I have read and understand that every reasonable effort will be made to keep my records confidential; however absolute confidentiality cannot be guaranteed.

☐ Yes ☐ No

I understand that submitting the completed surveys means that I give my consent to participate in this study.

☐ Yes ☐ No

Please click **here** to print a copy of your online consent and authorization form.