Informed Consent Form – Implementation Phase

Official Study Title:

Guideline to Implementation: A Rapid Clinical Care Pathway to Care for Patients Affected by Chronic Constipation

NCT Number:

NCT07032376

IRB Approval Date:

June 4th, 2026

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:
Guideline to Implementation: A Rapid Clinical Care Pathway to Care for Patients Affected by Chronic Constipation

Company or agency sponsoring the study:
National Institutes of Health

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator: Eric Shah, MD, MBA, Department of Internal Medicine, University of Michigan

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. In your decision to participate in this study, consider all of these matters carefully.

This research is studying how the availability of an FDA-cleared point-of-care, bedside device to evaluate constipation fits into the usual office visit with your care provider. This research will involve making the device available to you and your care provider in the gastroenterology office to perform during your gastroenterology office consultation. In this research, you will be asked to complete a survey prior to your gastroenterology office consultation. There are no additional study visits for this research study. Your health-related information will be collected for this research study.

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 embarrassment, discomfort, and irritation of the anal canal with the unlikely possibility of spotting of red blood such as due to hemorrhoids. In order to minimize each participant's risks, your expert gastroenterology care provider may perform the digital rectal exam followed by placement of the FDA-cleared study device that evaluates pelvic floor function (and removal if necessary, at bedside). This is the same gastroenterology

care provider who will see you as part of your clinical care in the same appointment, regardless of study participation. As with any research study, there may be additional risks that are unknown or unexpected. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by allowing accurate in-office evaluation and management of constipation. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be the time (approximately 10 minutes) it takes to complete the baseline survey before your routine gastroenterology office visit and the time (two minutes) that it takes to complete the point-of-care device with your care provider during your gastroenterology office visit.

Participation in research is completely voluntary. You can decide to participate or not to participate. Your decision whether or not to take part will have no effect on quality of your medical care.

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:

Constipation is a very common gastrointestinal condition. While many patients improve with laxative treatments, up to half of constipated patients are not satisfied with their treatment. In up to one-third to one-half of these patients who fail laxatives, constipation can occur due to pelvic floor muscle problems. For example, the pelvic floor might not be able to relax. We developed a point-of-care, bedside device that is cleared by the United States Food and Drug Administration which can be used during a routine rectal examination to find out if a patient has pelvic floor muscle problems. We also developed an electronic aid on the computer to help providers guide patient care for constipation that has not been cleared or approved by the United States Food and Drug Administration. We hope that these devices will help providers to accurately evaluate constipation at bedside, and in doing so allow patients to be more effectively treated.

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?

Patients at least 18 years of age that have a scheduled U-M Gastroenterology appointment to evaluate chronic constipation as a main complaint are eligible for the study. Patients that have taken narcotic pain medication within the last 30 days, or that have been scheduled for or undergone anorectal manometry testing or seen a pelvic floor physical therapist to treat constipation in the past 12 months, or that are pregnant are not eligible for the study.

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

218 patients are expected to participate at the University of Michigan.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

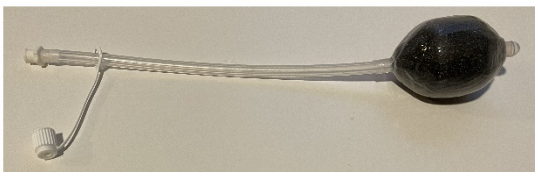
After you agree to participate and provide electronic informed consent:

1. You will see your gastroenterology care provider to evaluate chronic constipation in the office as part of your routine care. You will be asked to complete a research survey online within two weeks prior to this appointment using a link sent to your email address.
2. Your gastroenterology care provider may or may not perform the point-of-care bedside device during your office visit for routine care at their discretion and yours.
   a. In the examination room, you will then be asked to lay on your side on an examination table.
   b. A digital rectal exam followed by placement of the FDA-cleared study device will be performed by the gastroenterology care provider.
   c. The study device is a thin, flexible catheter connected to a soft, compressed foam-filled balloon. The study device will be placed no more than 6 inches into the rectum. After placing the study device, the balloon will be filled with air to mimic stool.
   d. You will be asked to strain to expel the study device as you lay on your side for up to two

A



B



minutes. If the device is not expelled, the device will be gently removed from your rectum at bedside. This will add a maximum of two minutes to your office visit.

3. There are no additional study visits for this research study.

4.2 How much of my time will be needed to take part in this study?
The survey takes 10 minutes to complete and must be completed before your upcoming routine care office consultation. The time that it takes to complete the point-of-care device with your care provider adds approximately two minutes to your routine gastroenterology office visit.

4.3 When will my participation in the study be over?
In addition to the time above, we will collect information from your medical records for one year of follow-up. The entire study is expected to last about 5 years.

4.4 What will happen with my information 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 embarrassment, discomfort, and irritation of the anal canal with the unlikely possibility of spotting of red blood. In order to minimize each participant's risks, a gastroenterologist will perform the digital rectal exam followed by placement of the study device (and removal if necessary, at bedside). As with any research study, there may be additional risks that are unknown or unexpected.

- The device has been constructed with similar characteristics as a current standard-of-care pelvic floor testing device. Therefore, the risk of damage to the subject's anorectal tissue in the case that the novel device does not function as intended is small in comparison with the benefit of the development of this device that could eventually provide point-of-service information about a patient's anorectal function. This information will streamline the care of millions of patients suffering with dyssynergic defecation.
- Psychosocial Harm: Rare - Procedure could be embarrassing or upsetting to the subject. To minimize this risk all subjects will be thoroughly debriefed before the procedure and required to sign informed consent.
- Potential Health/Physical Harm: Rare - The novel device, has been constructed with smooth layers, minimizing edges that could damage a subject's tissue.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

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?

If you are injured or become ill as a result of research procedures, you will be provided with medical treatment, but the following organizations do not plan to pay for this treatment.

- Michigan Medicine

If you have any questions or concerns about the legal responsibility of these organizations, please call the University of Michigan Office of Risk Management and Insurance at (734) 764-2200 during normal business hours.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

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, others may benefit from the knowledge gained from 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. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Participation in research is completely voluntary. You can decide to participate or not to participate. Your decision whether or not to take part will have no effect on quality of your medical care.

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?
Participation in research is completely voluntary. You can decide to participate or not to participate. Your decision whether or not to take part will have no effect on quality of your medical care.

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 researcher's telephone number listed in Section 10.1.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs. This means that you or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study. It is not the general policy of the federal funding agencies to compensate or provide medical treatment for human subjects in federally funded studies.

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?

No. You will not be paid for taking part in this study.

8.3 Who could profit or financially benefit 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.

Both Dr. Shah and the University of Michigan have an interest in one of the devices used in this study. In the future, they might receive a part of the profits from any sales of this device.

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?

Your research data will be stored in the HIPAA-compliant research drive offered by Michigan Medicine that contains your research information. Your gastroenterology care provider may enter the results of the research device into your medical record during their office visit but will not have access to your survey data. We will retain your data for a maximum of seven years or longer if required by the Food and Drug Administration, after which the research data will be destroyed.

This research will be covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others]. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

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.)
- Demographic information
- Personal identifiers
- Health plan/health insurance records
- Any records relating to condition, the treatment received, and response to the treatment
- Billing 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.
- Information about your study participation may be included in your regular UMHS medical record.
- 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 will not expire unless you cancel it. 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:

- 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: Eric D. Shah, MD
Mailing Address: 1500 E Medical Center Drive
Telephone: (888) 229-7408
Email: umichgi-innovation@med.umich.edu

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: 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 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/Assent 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/yyyy): _____

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/yyyy): _____