Wearable Transcutaneous Electrical Acustimulation for Gastroparesis

NCT05362578

Date of IRB Approval: September 12, 2024

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

Wearable Transcutaneous Electrical Acustimulation for Gastroparesis

Company or agency sponsoring the study:

The Department of National Institutes of Health, Health and Human Services.

Names, degrees, and affiliations of the principal investigator:

Borko Nojkov, MD, Michigan Medicine, Department 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 childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

This study is testing something called “transcutaneous acustimulation” which means you will receive a mild electrical shock at known acupuncture stimulation points (i.e. acupuncture doesn't provide energy or an electric shock to the skin). The aims of this project are to study the effects of wearable transcutaneous electrical acustimulation (TEA) on gastrointestinal (GI) symptoms, gastric motility (the process by which food travels through the digestive tract), and possible mechanisms of gastroparesis (A condition that affects the stomach muscles and prevents proper stomach emptying). This research is studying the use of a new device in small numbers of people to learn about its safety and effectiveness as a treatment for gastroparesis. Researchers want to understand how the device works in your body and how your body will react to it. The aims of this project are to study the effects of the wearable TEA on gastrointestinal symptoms, gastric motility, and possible mechanisms. Your health-related information will be collected for this research study.

This study involves a process called randomization. This means that the location of stimulation you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance generated by computer, to compare different treatments or procedures. We will be dividing participants into two groups, a sham group and a treatment group. The treatment group will receive stimulation at a location which has shown improvement of symptoms in other studies. The sham group will receive stimulation at an inactive point. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

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 new symptoms from use of the TEA device such as an allergic reaction to the electrodes or discomfort from the stimulation. More detailed information will be provided later in this document.

This study may offer some benefit to you now via improvement of your gastroparesis symptoms. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 12 weeks.

You can decide not to be in this study. Alternatives to joining this study include standard-of-care medical therapy or diet modification.

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 below.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The device being studied, the Transcutaneous Electrical Acustimulator (TEA), will deliver weak electrical current at two specific points, one at the leg and the other at the arm with stimulation parameters known to improve gastrointestinal motility. The study team would like to assess if the device will impact the GI symptoms and gastric motility in study participants with gastroparesis.

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?

Subjects enrolled in this study must be diabetic adults with at least a 3-month history of diabetic gastroparesis symptoms (e.g., vomiting, nausea, early satiety, bloating, or epigastric or abdominal pain). The remaining eligibility criteria will be confirmed via telephone interview and by chart review prior to the first visit. The inclusion and exclusion criteria will also be checked on the day of visit one prior to enrollment.

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

We expect to enroll 60 subjects with gastroparesis into the study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

You will have 2 research visits at the Gastrointestinal Physiology Lab at The University of Michigan. Visit 2 will be approximately 8 weeks after visit 1. 4 weeks after visit 2 (F-1), the study will end and you will mail us the stimulators. Procedures done at both visits will be approximately the same. . You will be asked to complete brief phone calls each week during the study. Questions will be focused on your symptoms and possible side effects of the TEA.

Assessment	**V1**	**V2**	**F1**
	Week 0	**Week 8**	**Week 12**
Pregnancy test (women of childbearing potential)	X	X	
Inclusion/Exclusion Criteria	X		
Medical History	X		

Vital Signs	X	X	
Gastroparesis Cardinal Symptom Index – Daily Diary (GCSI-DD)	X	X	X
Short Form Health Survey to measure Quality of Life (SF-36 (QoL))	X	X	X
Hospital Anxiety and Depression Scale (HADS)	X	X	X
Gastric Accommodation	X	X	
Abdominal Pain	X	X	
Electrogastrogram (EGG)	X	X	
Electrocardiogram (ECG)	X	X	

Procedures at each visit are explained below:

Pre-Visit 1:

You will need to begin fasting for your visit the next day by eating no solid food from midnight. You may drink no more than 120 mL (4 ounces) of plain, unflavored water between midnight and 1 hour before the test.

Visit 1:

You will come to the study location, the Gastrointestinal Physiology Lab within the University of Michigan Hospital in Ann Arbor. The visit will take place in one of the private rooms within the lab. If you are a woman of childbearing potential: you will complete a urine pregnancy test provided by the study team. If your pregnancy test is positive, you will be excluded from further participation in the study and will not complete the visit.

Questionnaires: You will need to complete the questionnaire forms prior to the first test.

In the morning, you are required to come to the same lab. The 3-in-1 gastric functional test is a noninvasive method to assess the gastric motility and abdominal pain. The test includes recording of EGG, ECG, and a water drink test for gastric accommodation, or to test how well your stomach responds to a meal. The ECG recording: Three ECG electrodes will be placed on your body surface and connected to an ECG device. The skin area where the electrodes to be placed will be carefully cleaned using skin-prep materials.

The EGG recording: Six surface electrodes connected to the EGG machine will be placed on your upper abdominal areas. The skin area where the electrodes are to be placed will be carefully cleaned.

Water Drink Test: You will be asked to drink water at a speed of 60ml/min (2 ounces/minute) until reaching your maximum tolerance.

Both EGG and ECG will be first recorded for 30 minutes in the fasting state. Then the water drink test will be performed by the study team member. After that, EGG and ECG will be recorded for another 30 minutes and the symptoms of bloating, fullness, nausea, and pain will be assessed at 10, 20, and 30 min during the recording. At the completion, approximately 2 hours after arriving, you may leave the lab and can have regular foods and drinks.

Study Device:

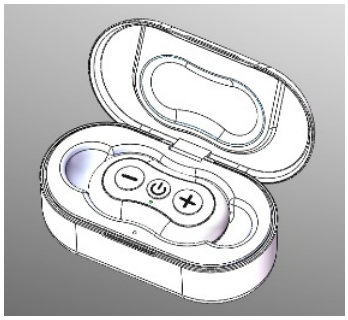
Training on the use of TEA device:

After completion of visit 1, you will be trained to find the location of stimulation points and how to operate the TEA device.

There are four possible placements of the device – two on the forearm and two on the lower leg. Two points will be known as treatment points, meaning they may offer improvement of gastroparesis symptoms. The other two points are known as sham points, or control points, meaning they will not provide any therapeutic benefit. All participants will receive electrical stimulation regardless of the location they are assigned. The placement of the

device will be determined by a process called randomization. This means you will not know if you are assigned to the treatment or the sham group.

After the device placement, electrical stimulation will be performed for a period of a few minutes (5-10 min) so that you can feel and learn how to operate the device. You will also be taught how to store and charge the device when it is not in use. The storage box can also be used as a charging unit.



Surveys will be sent to you via email through a program called Redcap, and you will receive one email per day with the link to that day's surveys. If you do not have email access, paper surveys may be provided.

Home Use of the Study Device:

The study device will be used twice daily for 45 minutes at a time. One session will be done each morning and one will be done each evening. You will be trained on the use of this device at your first visit, but if any issues come up, you may contact the study team.

If you feel the device is causing you any issues, please reach out to the study team. You may contact Benson Hang, the study coordinator, at behang@med.umich.edu or you may contact Dr. Borko Nojkov, the PI of the study. More information can be found in section 8.1

Follow-up:

During the 8-week period between Visit 1 and Visit 2, as well as after Visit 2 and until Week 12, subjects will be called once per week to ensure the surveys are being completed During this phone call, the study coordinator will also ask if the subjects are experiencing any symptoms or if any adverse events have occurred.

Visit 2: Following the first 8-week period, there will be another visit which will follow the same protocol as Visit 1.

Following Visit 2, there will be by a 4-week open-label period. This means you will be informed of which type of treatment you received for the first 8 weeks. For the remaining four weeks you will continue with one of two options depending on the type of treatment in the first 8 weeks. If you were assigned to the treatment group, you will be asked to stop treatment for the last four weeks of the study and to continue daily surveys. If for the first 8 weeks, you were assigned to the sham group, you will be instructed on the correct placement of the study device and will continue treatment at the new location for the next four weeks and continue the daily surveys.

Surveys will be distributed and returned through one of the following methods at your preference: 1). continue to use REDCap 2). hard copy printed by study team and given to you at visit 2 and mailed or scanned and emailed back to the study team, 3). emailed an electronic PDF copy to you to be completed and returned

After using the research device at home for 12 weeks, you will return it to the study team. At this point, your study participation is over. At visit 2, subjects will be given a pre-labeled shipping container to mail the devices back to the study team.

For some research studies, such as the one you are being asked to join, it is important that you do not learn the results of certain tests, such as the 3-in-1 gastric functional test. Whether you intend it or not, sometimes learning this information may make you change your actions and behaviors in ways that could impact the outcome of the study.

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

Each visit entail a water drink test together with the recordings of the EGG and ECG, lasting about 2-3 hours.

There will be 2 visits in total; the interval between the two visits is 8 weeks. There is an additional 4-week follow up period. During the 12-week study, there will be brief phone visits each week. Each phone visit is expected to last 5-10 minutes. You will also be asked to complete one survey per day which will take about three minutes per survey, another survey once per week which will take about 5 minutes per survey, and a final survey once every 3 which will take about 15 minutes per survey.

4.3 When will my participation in the study be over?

Participation in the trial will last approximately 12 weeks. Access to the intervention being tested may not be available after the close of the trial.

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:

- Electrode pad placement on the skin: there is a possibility of allergic immune response to the electrode pad. The likelihood of this risk is rare, approximate incidence of <1%.
- Current flow through the skin during TEA therapy: during TEA therapy application, there is a possibility of uncomfortable sensation or pain at the skin, abnormal or involuntary movements, gastrointestinal disturbances (discomfort, changes in defecation), or nausea. However, the stimulation output will be set at a level that is well tolerated by the participant. In very rare occasions, you might experience rash or minor infection at the stimulation point that can be treated locally if needed. The likelihood of this risk is rare, approximate incidence of <1%.
- Water drink test for assessing gastric accommodation: Water drink test assesses reach the maximum tolerable volume of your stomach. You may have the feeling of fullness and nausea during and after the test, which usually goes away spontaneously.
- Electrogastrogram and electrocardiogram: These both use body surface electrodes. The skin where the electrodes to be placed will be well cleaned that may result in redness, which should go away quickly. The likelihood of this risk is rare, approximate incidence of <1%.
- Low Blood Sugar related to relatively prolonged fast…(particularly between Day 1 and Day 2 where the water test is done). Symptoms of hypoglycemia may present as excess sweating, excessive hunger, fainting, fatigue, lightheadedness, anxiety, blurred vision, headache, irritability, pallor, palpitations, sensation of pins and needles, sleepiness, slurred speech, tremor, or unsteadiness

The researchers will try to minimize these risks by:

All risks are rare. Staff who are skilled in performing the studies will care for you. Alternative procedures would not provide the same understanding of the influence of wearable TEA for gastroparesis participants.

To avoid hypoglycemia, the research staff will ask you to monitor your blood sugar and to bring a snack if their blood sugar becomes too low. Additionally, the research staff will have a juice or similar sugary drink available if needed. Furthermore, the study is being done in a clinical space with many medical personnel nearby throughout the study who can be called upon if needed. You may also wish to discuss with your physician or the study physician, Dr. Nojkov, about adjusting your diabetic medications in preparation for the fast. You will also be given the document: "Preparing for a Medical Procedure: Guidelines for Adults Not on Insulin Pumps" prior to arriving onsite.

If prior to a study visit, you become hypo- or hyper- glycemic, take appropriate action (drink a sugary drink or adjust your diabetic medication, respectively) and contact the study team to discuss whether rescheduling the study visit is appropriate.

Additionally, there may be a rare 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?

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**.** Michigan Medicine and the study doctor are responsible for determining whether your condition was the result of your participation in the study. Financial compensation for lost wages, disability, illness, or discomfort due to this condition or injury is not available. You do not waive any legal rights by signing the consent form.

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 may also experience improvement of your gastroparesis symptoms from being in this study. 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?

There may be other ways of treating your condition. These include altering your diet via the assistance of a dietitian or discussing medical therapy with your doctor. Although TEA is available as part of this clinical study

and is unlikely to be available at the conclusion of the study, you should check with the researcher and/or your primary care physician to discuss your options including how to obtain any alternative treatments and whether they must be obtained through a physician or require medical supervision.

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 harm will come 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.

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.

The study team has given you instructions about this research study. It is important that you follow these instructions carefully. If you get sick, have a medical complication, or are injured as a result of your being in the study, call Dr. Borko Nojkov immediately, at 888-229-7408. The doctor will either treat you or send you to another doctor for treatment. You will get free medical care at the UMHS for any complication, injury, or illness caused by the study drug, device, or procedure. The UMHS and the study doctor are responsible for determining whether your condition was the result of your participation in the study. The UMHS will pay for your treatment only if the need for treatment has been caused by the study drug, device, or procedure. 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?

Subjects will receive $500 and an additional $200 if they use overnight housing and are greater than 70 miles from Ann Arbor. The compensation is set at such a value based on the duration of the study (8 weeks) and length of each visit (need to stay at the hotel for a night), and the sensitive nature of the study. The payment will be issued at the completion of the first visit (30%), second visit (30%) and end of the follow-up period (returning of the TEA device and symptom forms) (40%). Subjects will not be paid for visits not completed. Local subjects will receive $150 after each study visit and $200 following the return of the TEA device. Subjects greater than 70 miles from Ann Arbor will receive $250 after each study visit and $200 following the return of the TEA Device.

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

This study is completely supported and paid by the National Institutes of Health. Transtimulation Research, Inc. is working with the University of Michigan to develop the TEA device used in this study. If the study is completed successfully, the company may later try to gain FDA approval for the clinical use of the device. The study is designed by the investigators at the University of Michigan. The University may apply for patents and Transtimulation Research, Inc. may license the patents from the University.

The company whose product is being studied: Transtimulation Research, Inc. has made the device to be used in 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 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 information will be stored in a locked cabinet or online virtually in a HIPPA compliant service with restricted access. Your research information will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record. Your protected health information will only be accessed by the clinical research team, such as the study coordinator, the PI, and the lab staff, all of whom are trained and HIPPA certified. Your protected health information will not be accessed or available to those who are outside the clinical research team.

This research is 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 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.)
- 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 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
- 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 finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.
- 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:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an 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: Borko Nojkov, MD
Mailing Address: Int Med-Gastroenterology, 3912 TC, 1500 E. Medical Center Dr, Ann Arbor, MI 48109-5362
Telephone: 734-936-9455

Study Coordinator: Benson Hang
Mailing Address: 102 Observatory Street, Ann Arbor MI, 48109
Telephone: 734-764-5753

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 Email: 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 a copy of 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 confidential research file and may be entered into your regular University of Michigan medical record.)*

You will also be given the document: "Preparing for a Medical Procedure: Guidelines for Adults Not on Insulin Pumps" prior to arriving onsite.

12. SIGNATURES

Consent 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 _____. 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.

Print Legal Name: _____

Signature: _____

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

Principal Investigator or Designee

I have provided this participant with information about this study that I believe to be accurate and complete. The participant 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): _____