Aurora IRB Stamp of Review	*Complete or apply a patient label*
Aurora IRB #: 17-120	
Version date: 10/23/2017	Medical Record #

Subject name: _____ Subject date of birth: _____

Aurora Health Care, Inc.
Consent to Participate in a Research Study

Study Title	Pilot study for the efficacy and tolerability of Senokot-S® in the treatment of diabetic gastroparesis
Study Investigator	Bradley Gose MD 414-385-2590
Sponsor	Aurora Research Institute and the Aurora Foundation

Why am I being asked to participate?

You are being asked whether you would like to voluntarily participate in a research study about diabetic gastroparesis because you were identified by your health care provider as being affected with this disease and may benefit from this study. Diabetic gastroparesis, sometimes called delayed gastric emptying, is a condition that slows or stops the movement of food from the stomach to the small intestine.

This form describes the study and what you would need to do. We will answer any questions you may have so that you can make an informed decision.

What is a research study?

A research study is an experiment, survey, or information collection whose purpose is to answer a specific question, such as:

- Does this work?
- Is it safe?
- What kind of treatment is better?
- How do people think or feel about this?

To answer these questions, doctors and scientists need volunteers to participate in research studies. These volunteers are called "subjects." The doctors and scientists who run the research study are called "investigators." Other people who help them run the study are called the "research team."

Sometimes a drug or device being tested makes research subjects better, and sometimes it doesn't. When you are a subject, the main purpose is to see if the study drug or device works and if it is safe. There may be side effects or risks to you, including some we don't know about right now.

This is a Phase 2 study. In a Phase 2 study, the drug is given to a larger group of people to see if it is effective and to further evaluate its safety.

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A research study has specific rules the investigator must follow. The study rules may say that subjects can't receive certain medications or treatments while they are in the study. We will explain the rules you will have to follow. If you can't or don't want to follow these rules, then you should not participate.

What is the purpose of this study?

In this study, we want to determine if the study medication, Senokot-S, helps to improve stomach emptying and symptoms in people who have diabetic gastroparesis.

Senokot-S is approved by the U.S. Food and Drug Administration (FDA) as an over-the counter medication to treat occasional constipation. Senokot-S is not approved by the FDA to treat patients with diabetic gastroparesis, and its use in this research study is considered to be investigational.

Who is sponsoring this study?

The sponsor for this study is Aurora Research Institute.

Where will this study take place?

This study will take place at Aurora St Luke's Medical Center. Dr. Gose will enroll a total of about 60 subjects in this research study.

What is involved?

As a subject, you will be responsible for:

- attending all study visits
- taking the study medication as directed
- completing the provided questionnaires
- telling the investigator if you are feeling bad or worse than before
- telling the investigator if you have any changes in medications during the study
- following the directions of the investigator and research team

If you agree to take part in this study, you will sign this consent form before any study-related procedures are performed. The investigator and research team will ask you questions and review your medical records to determine if you qualify to be in the study.

The following questionnaires are for research purposes only. This means you will only complete these if you agree to be in the study:

- This is a modified Gastroparesis Cardinal Symptom Index-Daily Diary (mGCSI-DD) questionnaire. This is a questionnaire that asks how gastroparesis affects your daily life. It will take less than 10 minutes to complete each time you are asked to do so.
- Complete a questionnaire about the other medications you take for symptoms of gastroparesis and about your bowel habits. It will take you less than 5 minutes to answer this questionnaire each time you are asked to do so.

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If you agree to take part in this study you will take the study medication, Senokot-S, for 28 days. You will be randomly assigned (like flipping a coin) to one of two study groups, one group will be given a higher dose of study medication, and the other group will receive a lower dose.. You will not be told what group you are randomized into. The study medication doses for both groups are within the current manufacturer's dosing guidelines.

Dr. Gose will tell you how much of the study medication you should take and answer any questions you have about taking the study medication.

The chart below will explain what you will do at each study visit.

What will happen at each study visit?

Visit	During this visit, you will	How long is this visit?	Reminders
Visit 1 (Screening)	• Review and sign this consent form first • We will review your medical history • Determine if you qualify for the study • Provide you with the study questionnaires	1-2 hours	Bring a list of all medications you take including any over the counter medications
Visit 2 (one week after Visit 1)	• Review your questionnaires to date • Assign you to a study group and provide you with your study medication • Provide you with your questionnaires for the remainder of the study	1 hour	Bring in your study questionnaires

Dr Gose will talk to you about reducing any medication you currently take for gastroparesis as can safely be tolerated while you are taking the study medication.

You are encouraged to call Dr. Gose at any time with health concerns related to study participation. Health concerns that may require immediate attention may include, but are not limited to, significant diarrhea and rectal bleeding.

After you finish the 28 days of Senokot-S, you will use a pre-addressed, postage paid envelope to mail your study questionnaires back to Dr. Gose. After you return the study questionnaires, your active participation in this study will be ended.

Dr. Gose will review the information you recorded on the study questionnaires. If any information is missing or he has questions about what you wrote, he may contact you to ask you follow up questions. Dr. Gose will contact you by telephone or e-mail, depending on which method is easier for you.

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Are there any risks to me?

There may be risks, side effects and discomforts if you choose to participate in this study. These can be physical, emotional, financial or social. The ones we know about are listed below.

There may be side effects from the study drug Senokot-S. Many side effects go away, but sometimes they can be serious, long-lasting, or may never go away. There may be other side effects that we don't know about yet, so be sure to tell the investigator about any unusual symptoms.

Risks of Senokot-S

Common	Rare but serious (fewer than 1 in 100 people)
• Diarrhea • Abdominal (stomach) cramps • Flatulence (gas) • Nausea • Urine discoloration	• Difficulty breathing • Severe abdominal pain • Rash/hives • Diminished bowel function with long term use • Rectal bleeding

You should not become pregnant while you are participating on this study. If you are a woman who can become pregnant, you should practice an effective method of birth control while you are taking the study medication, Senokot-S. Please talk to your primary care doctor if you have questions about what birth control method is right for you. If you become pregnant during the study you must tell Dr. Gose immediately. You will not be able to continue in the study if you become pregnant.

Questionnaire risks: You will complete questionnaires in this study. Some the questions may make you feel uncomfortable, like discussing your bathroom habits. These questions are very important for the study. If you think you will be uncomfortable answering these questions you should talk to Dr. Gose before agreeing to be part of this study.

Are there any benefits to me?

You may or may not benefit from being in this study. Your gastroparesis symptoms could improve in the following ways: less nausea, less bloating (feeling full), less abdominal pain.

It is also possible that your condition could stay the same or even get worse. We hope the information learned will help other patients with gastroparesis in the future.

How much will it cost to participate?

There will be no cost to you, or your insurance, if you agree to take part in this study.

In this study, the sponsor will pay for:

- The study medication, Senokot-S

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Will I be paid to participate?
You will not be paid to participate in this study.

How long will I be in the study?
You will be in the study for 5 weeks.

The study may be stopped early by the sponsor or the investigator. You could be asked to stop being in the study for any of the following reasons:

- for your safety
- if you do not follow our directions for this study
- if you become pregnant

If you stop being in the study early for any reason, we will ask you to do the following:

- notify the investigator of your decision

Do I have to be in this study?
You do not have to be in this study. If you start the study, you may stop at any time. There is no penalty or loss of benefits if you don't want to participate, and your decision won't affect your regular medical care.

You may decide to participate now, but change your mind and withdraw from the study anytime without penalty or loss of benefits. If you decide to withdraw before the last study visit, let the investigator know. There may be special procedures to follow for your safety.

If you don't want to be in this study, your other options include:

Alternate treatment	Potential risks	Potential benefits
Resume treatments previously prescribed to you by your physician including any diet recommendations or prescription medications	Persistence of gastroparesis symptoms, or side effects of previously prescribed medications	Relief of gastroparesis symptoms including less nausea/vomiting, abdominal bloating, or abdominal pain
Reglan (metoclopramide)	Involuntary muscle movements, seizures, and others as described in the medication's information	Relief of gastroparesis symptoms including nausea.

This is not a complete list. Your doctor can tell you about all your options, and their risks and benefits.

What if I am harmed from being in the study?
If you get hurt or sick from being in this study, you should seek medical treatment as needed. Be sure to tell the investigator as soon as possible.

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We will bill your insurance, if you have any, and you will have to pay your usual copays or deductibles. If you have Medicare, we may send information that identifies you to Medicare. If you do not have insurance or if your insurance does not cover your treatment, we will bill you for the costs of the treatment.

Will my records be kept confidential?

Your study records will be kept as confidential as possible. You can find out more in the section "Information about Confidentiality and HIPAA Authorization."

What if there is new information about this study?

If we learn any new information about this study that might make you change your mind about participating, we will tell you.

If you want to know the results of the study once it is over, you can ask the investigator.

Who oversees this study?

The Aurora Institutional Review Board (IRB) has approved this study. The IRB is a group of people who review all research studies at Aurora to check that they meet federal laws and ethical standards.

IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends and personal doctor before you decide.

Who do I contact?

If …	**You should contact**	**Contact information**
You are harmed by the research	Bradley Gose MD or Aurora Patient-Centered Research	414-385-2590 or 414-385-1873
You have questions about your rights as a research subject	Aurora IRB office	414-219-7744 (outside Milwaukee: 877-219-7744)
You have questions, problems, concerns, information, input or complaints about this research study	Bradley Gose MD or Aurora IRB office	414-385-2590 or 414-219-7744 (outside Milwaukee: 877-219-7744)

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Information about Confidentiality and HIPAA Authorization

The Privacy Rule of the federal Health Insurance Portability & Accountability Act (HIPAA) is a law that protects the confidentiality of your personal health information. This Authorization describes your rights and explains how your health information will be used and disclosed.

Why is access to my health information being requested?

To help answer the research questions, the investigator and research team will use and store personal health information about you. We are asking your permission to use and share it with others, as explained below. If you don't give this permission, you won't be able to take part in the research study.

What information will be collected and used?

When you are a subject, we will collect health information about you that also includes your name, address, telephone number, or other data that could identify the health information as yours. Under HIPAA, this health information is protected and can't be used without your permission, unless otherwise permitted by law. If you sign this authorization, you are giving permission for Aurora Health Care to use and disclose your personal health information as described below.

The following are examples of personal health information that may be collected for this study:

- results of tests and procedures
- information about your medical conditions and history

The collected information may contain your name, address, telephone number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, and/or other identifying information.

Who will see my protected health information?

By signing this Authorization, you allow the Aurora Research Institute research team to use your personal health information to carry out and evaluate this study. You also allow access to your personal health information (including direct access to your medical records at Aurora) to the following:

Who may have access:	**Purpose:**
The sponsor of the study and anyone working on its behalf	To oversee the study and make sure the information is correct
Aurora consultants and employees, including IRB members	To protect the rights and safety of subjects and make sure the study information is correct
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries)	To make sure applicable laws are being followed

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Who may have access:	Purpose:
Organizations that grant accreditation to hospitals and research programs	For Aurora to remain accredited

Will you keep my health information confidential?

We will keep your personal health information as confidential as possible. We will only share it as described above or if required or permitted by law. It is not likely your information will be given to others without your permission. However, once your information leaves Aurora, we can't control how it is used, and it will no longer be covered by the HIPAA Privacy Rule.

Will other people know that I was in this study?

If the results of this study are published, your name or other personal information will not be included.

How long will my personal health information be used?

Access to your personal health information begins as soon as you sign this form. This authorization expires when the study if finished.

What if I change my mind?

If you don't want us to use and disclose your personal health information anymore, you must let the investigator know in writing. If you need help with this, you can ask the research team or call the Aurora IRB office at 414-219-7744 (outside Milwaukee: 877-219-7744).

If you withdraw permission for us to use your personal health information:

- you can't continue in the research study
- we will stop collecting health information from you
- we will still use and disclose any information that we gathered while you were a subject
- there will not be any penalty or loss of benefits to which you are otherwise entitled

Can I see my study records?

You have the right to see and get a copy of your study records. However, by signing this Authorization, you agree that you will not be able to see your study records during the research study. You can only see them once you complete the study or drop out.

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Subject name: _____

- I have read this form and the research study has been explained to me.
- I have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.

_____

Subject signature Date Time

_____

Witness signature (if applicable*) Date Time

**Use when the subject cannot read the consent (for example, subject is blind, illiterate, or does not speak English). The witness must be present for the entire consent discussion. The witness signature means that the information in this document was presented to the subject, and the subject appeared to understand it.*

For Site Use only:

- I have carefully explained to the subject the nature and purpose of this study.
- The subject has been given enough time and an adequate place to read and review this form.
- The subject has had a chance to ask questions and receive answers about this study.

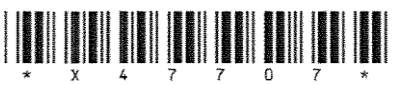
_____

Name of person obtaining informed consent (print) Title Phone number

_____

Signature of person obtaining informed consent Date Time

Per state law, a physician investigator should conduct the risk/benefit/alternative discussion and complete the above signature if there is a medical intervention required of the research and a treatment consent would be required for that intervention.



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Risk/Benefit/Alternatives Discussion

I have explained and discussed with the subject or his/her legally authorized representative

- The nature of the research
- Potential risks and benefits
- The alternate treatments available to the subject and the benefits and risks of each

_____

Name of person providing this information (print) Title

_____

Signature of person providing this information Date

DOCUMENTATION OF INFORMED CONSENT:

- ☐ All elements of the study contained in this document were discussed with the subject.
- ☐ The subject had the opportunity to ask questions, all questions were answered, and the subject expressed understanding.
- ☐ The subject gave written informed consent before any research-related procedures began.
- ☐ The subject received a copy of the signed and dated consent form.

_____

Signature of person obtaining informed consent Date

FILE A SIGNED COPY OF THIS FORM IN THE PATIENT'S MEDICAL RECORD (if applicable).
Keep the original in the investigator's research records. .
Form IC 701A v. 4/10/17

THIS PAGE IS FOR DOCUMENTATION ONLY. IF GIVEN TO SUBJECTS, IT MAY BE BLANK.

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