ClinicalTrials.gov Results Cover Page

Study Title: Axonics SacRal NeuromodulaTIon System RegisTRY Study

Study number: 105-0076

NCT05064384

Document name: Informed consent form

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Informed Consent Form
and Authorization to Disclose Protected Health Information

Sponsor / Study Title:	**Axonics Modulation Technologies, Inc. / "Axonics SacRal NeuromodulaTIon System RegisTRY Study : ARTISTRY"**
Protocol Number:	**105-0076**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

A. General Information

Please read this consent form carefully. It explains the things you will be asked to do during the study. If you decide to be in the study, you will be asked to sign and date this consent form. A copy of the signed and dated consent form will be given to you to keep.

Axonics is the Sponsor of the study.

You are being asked to think about joining this clinical registry study. A registry study is simply a study that observes outcomes of an already approved therapy in a real-world population. You are being asked to participate because you and your doctor have decided that you are a candidate for the Axonics Sacral Neuromodulation (SNM) System to treat your urinary and/or bowel dysfunction. These conditions may include one or more of the following:

- Urinary Retention (UR): a problem of not being able to empty your bladder fully or at all
- Fecal Incontinence (FI): a problem of accidental leakage of stool
- Overactive Bladder (OAB) including urinary urgency incontinence (UUI) and urgency-frequency (UF): UUI is a problem that can cause accidental leakage of urine with a sudden desire to urinate and you are not able to make it to the bathroom in time. UF is a problem associated with having to go to the bathroom frequently (more than 7 times) during the day and possibly getting up more than once at night.

If you previously had an InterStim SNM System, and now are receiving an Axonics SNM System, you may be asked certain questions about your experience with the InterStim SNM System.

B. What are my responsibilities if I agree to be in the study?

The following are important responsibilities that you need to agree to while you are in the study:

- Follow your study doctor's instructions regarding your therapy.
- Come to all of the scheduled clinic visits.
- Complete all of the questionnaires that are part of the study that are described in this consent form.
- At the time of consent to the study, you cannot be breastfeeding or pregnant.
- You must inform your study doctor and the study staff of any changes in your health or medications, and any new surgeries during the study.

C. Do I have to be in this study?

Participating in research is voluntary. You do not have to be in this study. This research study is for research purposes only. The only alternative is to not participate in this study.

The decision to join this study is completely up to you. You may decide not to be in the study or to leave after joining without any penalty or loss of benefits to which you are otherwise entitled.

If you decide to be in the study, you may withdraw from the study at any time. You may withdraw without giving a reason. If you want to withdraw from the study, please inform your study doctor.

The study doctor or the Sponsor may remove you from the study at any time for any reason. You may be removed without your permission. Some reasons that you can be removed from the study are as follows:

- If you do not or are unable to fill out questionnaires
- Any other reason as determined by your study doctor or the Sponsor
- U.S. Food and Drug Administration, the Institutional Review Board (IRB), or government agencies also have the right to stop the study at this site at any time

Certain people will continue to have access to the data collected during your participation in the study after you are withdrawn from the study. These people include: the study doctor, designated study staff, the Sponsor representative, and the U.S. Food and Drug Administration (FDA).

We will tell you about any new information that may affect your health, welfare, or choice to stay in the study.

D. What is the purpose of the study?

Axonics has an FDA-approved device called the Axonics Sacral Neuromodulation (SNM) System which is indicated to treat the urinary and bowel disorders listed above. This study is being done to assess the post-approval clinical outcomes in a real-world population. The primary aim

of this study is to assess the device effectiveness and performance in reducing the symptoms of urinary retention, fecal incontinence, and overactive bladder. The outcomes will be measured by the questionnaires that we will ask you to complete, along with information about device performance and information from your medical records related to treatment for your condition.

E. Study Overview

This is a prospective registry study. The purpose is to assess the post-approval clinical outcomes of the FDA-approved Axonics SNM System as an aid in the treatment of OAB, UR and FI in a real-world population. Here is a brief explanation of what these terms mean:

Prospective: a type of cohort study in which participants are enrolled prior to being treated with the device. The participants will be implanted and receive treatment with the Axonics SNM System and their response will be followed over time.

Registry Study: a type of study which simply observes outcomes of an already approved therapy in a real-world population.

Post-approval: after FDA approval of the Axonics device.

The study will consist of approximately 300 participants to be enrolled in medical centers in the United States and Canada. These participants, like you, have a planned Axonics SNM System implant procedure for the treatment of their symptoms of UR and/or FI, and/or OAB. There will be approximately 30 sites that will be enrolling participants in this study.

Enrollment & Baseline:

Once you have signed and dated the informed consent form, you will be asked to fill out a baseline questionnaire on your symptoms. If you meet all the study requirements you will be included in the study. You will be scheduled for your Axonics trial evaluation whether or not you are included in the study. Your doctor will discuss the details of the procedure with you.

You will be asked to follow your physician's study doctor's instructions regarding follow-up visits after implant. You will be asked to complete questionnaires either in person at an office visit or remotely by phone/computer. These visits are scheduled at the following time intervals: **during trial evaluation,** at **1 – 4 weeks after the implant, and 6 months** and **1 year** after your implant date. The length of your participation in this study will be approximately 1 year.

Study Follow-Up Visits:

During the study follow-up visits, you will be asked questions about:

1. Your general health.
2. The function of your implanted device.
3. How your bladder and bowel symptoms are doing since the implant.

Your study doctor or their study staff will let you know the exact dates and times of your visits. At those visits, you will be asked to fill in questionnaires related to your bladder and/or bowel symptoms. These questionnaires usually take less than one hour to complete. The purpose of these questionnaires is to find out about your quality of life and how effectively the treatment may be working for you.

F. What are the possible risks during the study and precautions to be followed?

There are no physical risks to you beyond what is being explained by your physician from your standard treatment.

Warnings and Precautions

Your doctor will discuss the precautions to be taken with an implanted Axonics SNM system.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled "How will my privacy be protected?"

Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

There may be risks which are currently unknown.

G. Will there be any benefit to me by being in this study?

What is learned in this study may further treatment of patients suffering from UR, FI, and OAB in the future. There are no additional benefits to you from your taking part in this research.

H. What happens when the clinical study stops?

Once the study has ended, you will be exited from the study. Your care will continue per standard practice with your physician.

I. What will happen if I don't want to continue to be in the study?

Your choice to participate in this study is voluntary and is completely up to you. You are free to withdraw your consent to participate in the study at any time. In order to withdraw, you must inform your study doctor. There will be no penalty or change in your care if you decide to withdraw from the study. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

Certain people will continue to have access to the data collected during your participation in the study after you are withdrawn from the study. These people include: the study doctor, designated study staff, the Sponsor representative, Advarra IRB [or insert Local IRB Name] and the FDA.

J. What if new relevant information becomes available?

Your study doctor will tell you about any new information that may affect your health, welfare, or choice to stay in the study.

K. Is there any cost to me to be in this study?

There is no cost to you for participating in the study. You or your insurance company will not be charged for any study-related visits.

L. Will I be paid to be in this study?

«Compensation»

If you agree to take part in this research study, you will be paid for your time and effort. You will be compensated for your time for attending study visits to cover expected expenses. Expected expenses include your travel (mileage, parking, transportation, childcare) to and from your study doctor's office. You will be paid for the visits you complete according to the following schedule:

Visit	Baseline	Trial Period	Implant	1-Week Visit	6-Month Visit	1-Year Visit	Unscheduled
Subject Stipend	**$ 75**	**$ 50**	**$ 75**	**$ -**	**$ 25**	**$ 25**	**$ -**

If you withdraw from the study, you will receive an amount based on the visits that you have completed. If you miss any visits, you will not be reimbursed for those visits. How and when you will be reimbursed will be explained to you by the study doctor or study staff.

You will be paid _____ ***["after each visit," "annually," "bi-weekly," etc.]***

You will not share in any financial benefits from any products, tests, or discoveries that are developed as a result of this study.

M. How will my privacy be protected?

You will be asked for information about your past and present health. This information will cover health conditions and medications. You will also be asked about your experience with the Axonics device. The results of the questionnaires that will be collected as described in this informed consent form will be documented.

Your signature and date on this consent form gives permission for the study staff to collect and use information that can identify you. Your identity and records will be kept as confidential as possible as required by law. Your identity will not be made publicly available. Except as required by law, you will not be identified on any study form or sample collected from you.

These forms will not include your name, government identification number, address, telephone number or any other direct personal identifier. Instead, the study doctor will use your initials and you will be assigned a participant identification (ID) number. The study doctor will keep a list that matches participant ID numbers to participant names. The study doctor will not send that list to the study Sponsor. However, the study forms will contain other information about you. This may include your age, sex, and medical history. It is possible that this other information could be used to identify you even though your name does not appear.

The study doctor and study staff will have access to your medical records and your study information. This information will be provided to the Sponsor and organizations hired by the Sponsor to monitor the progress of the study. The FDA and other governmental agencies in the United States, as well as other countries, may also have access to your study information and medical records. The FDA is the US Food and Drug Administration. In addition, the following groups of people may also be able to see information about you and may use the information to conduct the study:

- The study staff that takes care of you and other study participants
- Any laboratories, pharmacies, or other individuals and organizations that use your health information as part of the approved plan for the study
- The designated peer review committees. These include Advarra IRB [or insert Local IRB Name].
- Contract Research Organization (CRO)

The Sponsor will use the data from this study to carry out the purposes of the study and to conduct other related studies. Other studies may include support for marketing applications, publications, and development of educational materials. You will not be identified by name in any of these materials.

By signing and dating this consent form, you agree that you will not be able to have access to your personal health information related to this study until the study is over and all study related activities are completed. This is done to maintain the scientific integrity of the study. After the study is complete, you can obtain access to your information in writing through your study doctor.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR STUDY PURPOSES

What information may be used and given to others?

The study doctor and study staff will get your personal and medical information. This includes:

- Questionnaires
- All information in a medical record
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition
- Records about study devices

- Mental Health information: diagnosis and treatment of a mental health condition

Who may use and give out information about you?
The study doctor and the study staff.

Who might get this information?
- The Sponsor of this clinical study. "Sponsor" means any persons or companies that are:
  - working for or with the Sponsor, or
  - owned by the Sponsor
  - If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record.

Your information may be given to:
- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported,
- Advarra IRB [or insert Local IRB Name]

Why will this information be used and/or given to others?
- to do the registry study,
- to evaluate the results, and
- to make sure that the study was done correctly.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this registry study.

May I review or copy my information?
Yes, but only after the registry study is over.

When will my permission end?
There is no date at which your permission ends. Your information may be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign and date this authorization document.

May I withdraw or revoke (cancel) my permission?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address listed on page one of this form. If you withdraw your permission, you will not be able to

stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

N. <u>Will the information about me be made public?</u>
The results of this study may be published in scientific journals and presented to the public. Information that could identify you (like your name) will not be used in any publication or presentation.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

O. <u>Whom to contact about this study</u>

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact [or insert Local IRB Contact]:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **<u>toll free</u>**: 877-992-4724
- or by **<u>email</u>**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: <u>Pro00047130</u>.

Advarra is a group of people who perform independent review of clinical studies. Although Advarra IRB has approved the information provided in this informed consent form and has granted approval for the Principal Investigator to conduct the study, this does not mean Advarra IRB has approved your participation in the study.

Advarra will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact Advarra if the study staff cannot be reached or

if you wish to talk to someone other than the study staff.

P. <u>What does my signature and date on the consent mean?</u>

I have read the document. I am aware that I am being asked to participate in a clinical study. I had the opportunity to ask questions and had them answered to my satisfaction.

I voluntarily agree to participate in this study.

I do not give up any of my legal rights by signing and dating this consent document. I will be given a copy of this signed and dated informed consent form for my own records.

Signature of study participant	Date
Print Participant's Name	
Signature of person who explained this study	Date
Print name of person who explained this study	