**ADDENDUM TO PLATFORM PROTOCOL**
**CONSENT FORM: Novaremed, NRD135S.E1**

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|---|---|
| **Sponsor / Study Title:** | **Massachusetts General Hospital, CTNI / "Platform Protocol to Assess Treatments for Painful Diabetic Peripheral Neuropathy"** |
| **ISA Title:** | **A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of 80 mg daily of NRD135S.E1 Versus Placebo in Adult and Elderly Participants with Painful Diabetic Peripheral Neuropathy (SERENDIPITY-1).** |
| **Protocol Number:** | **EN21-PP** |
| **ISA Number:** | **EN21-01** |
| **Principal Investigator: (Study Doctor)** | **«PiFullName»** |
| **Telephone:** | **«IcfPhoneNumber»** |
| **Address:** | **«PiLocations»** |

# KEY INFORMATION ABOUT THIS STUDY

This addendum to the Platform Protocol (PP) consent form includes information specific to the study treatment to which you have been randomly assigned. This form provides additional information that was not included in the PP consent. You are being asked to review this consent form because you have met the requirements to participate in the PP, and you may be eligible for the Novaremed study treatment. The active study drug in this treatment is NRD135S.E1.

All other sections of the PP consent form that you signed previously still apply. This includes the information about privacy and storing biological samples for future use. Please refer to the PP consent form for any questions you might have. A copy can be provided to you again, if requested.

You are being asked to take part in a research study by the Massachusetts General Hospital (MGH). You are being asked to participate in this study because you have painful diabetic peripheral neuropathy (PDPN), also known as diabetic neuropathy. Before you decide to participate, it is important for you to know why the research is being done and what it involves. This includes any potential risks to you or benefits you might receive. This study is being sponsored by MGH Clinical Trials Network and Institute, through a grant from the National Institutes of Health (NIH).

This research study will evaluate a new experimental drug called NRD135S.E1 as a possible treatment for PDPN. This study also will look at the safety and effects of NRD135S.E1 on your pain.

**Participation in this study is completely voluntary.**

- Read, listen to an audio recording or verbal explanation regarding the information closely. Talk about it with family, friends, and your primary doctor if you want.
- Ask a member of the study team about anything that is not clear or that you would like more information about.
- Take your time to decide if you want to participate.

You do not have to participate in this study. If you choose to participate, you will need to sign and date this consent form. Your signature and date will show that:

- You read the information in this document, listened to an audio or another person read it to you.
- You were able to discuss any questions or concerns you had with a study team member.
- You would like to participate in this study.

## WHY IS THIS RESEARCH STUDY BEING DONE?

We are doing this research to find out if a new experimental drug, NRD135S.E1, has an effect on PDPN. Researchers developed NRD after they heard about a village in Siberia that used tea to treat different health problems. They figured out which ingredient could reduce pain and improved that ingredient chemically. Then they turned it into a pill and named it NRD. NRD135S.E1 showed a decrease in pain after 3 weeks of study treatment when compared to placebo in a small study of 88 participants. A placebo is a pill that looks like the study drug but has no active drug. This study will see if these results are the same with longer treatment. NRD135S.E1 is an oral drug (taken by mouth). We also want to find out if NRD135S.E1 is safe to take without causing too many side effects. NRD135S.E1 is not approved by the U.S. Food and Drug Administration (FDA). This means that NRD135S.E1 can only be used in research studies. This study will look at one dose of NRD135S.E1, 80 mg per day. This study will compare the study drug to a placebo. You have an equal chance (like flipping a coin) of being randomly assigned to the active study drug or placebo. Neither you nor your study team will know which. However, your study doctor can find out in case of an emergency. Even if you are assigned to the study drug, you might be given placebo for a short period (days) at some point during the study. Throughout this form, the active drug and placebo will be called study drug.

This study will include about 122 participants, 18 years of age or older with PDPN. This clinic is one of about 24 centers across the U.S. that will be part of this study.

## HOW LONG WILL I TAKE PART IN THIS RESEARCH STUDY

If you choose to sign and date this consent form, your participation in this study will last about 22 weeks. You will receive study drug for about 13 weeks. You will need to visit the study site at least 7 times during the study. About 20 days after your last visit to the study site, a member of your study team will call you on the phone. They will ask you how you have been doing since taking the last dose of the study drug. They will also ask if you experienced any side effects since your last visit.

You may be asked to attend the research site for extra visits at any time during the study if the study doctor decides that this is better for your safety.

## WHAT ARE KEY CONSIDERATIONS FOR YOU TO PARTICIPATE IN THIS STUDY?

You may benefit from participating in this study. However, there is no guarantee that you will get any benefit from being a part of this study. If you choose to participate in this study, you will help researchers determine if this new experimental pain treatment helps people with PDPN.

- You may need to stop taking some of your current pain medications including pills, creams, patches, marijuana, cannabidiol (CBD) oil, etc. Acetaminophen (commonly known as Tylenol) is the only allowable pain medication other than the study drug. Acetaminophen is not provided by the study.
- You may need to take time from work or other responsibilities for study visits and procedures
- Your pain could worsen while participating

The sections below describe the study completely and potential risks from the study drug should you decide to participate.

## DO YOU HAVE TO PARTICIPATE IN THE STUDY?

- No, you do not have to participate in this study.
- If you decide to participate, it should be because you want to volunteer for this type of research. You can stop participating at any time.
- You will not lose any services, benefits, or rights you normally receive if you decide not to participate in this study.

## WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The study doctor is the person in charge of this study at this study site. If you have questions, suggestions, or concerns about this study, please contact the study team. If you want to stop participating in this study after signing and dating this consent form, please contact the study doctor using the contact information on the first page of this form.

## WHAT WILL HAPPEN IF YOU PARTICIPATE IN THE STUDY?

Study tests, procedures, and requirements are described in this section. Let the study team know if you have questions about these activities. After discussing the study activities, you will be asked if you want to sign and date this consent form. No study procedures will be performed until this consent form is signed and dated. After you sign and date this form, you will receive a copy and the study team will start the study activities.

After you are randomly assigned (like flipping a coin) to your study drug, you will come in for in-person visits. Most of these visits will take about 1-3 hours each time. You will have several blood draws during the study. Some of the blood collected from you during your participation in this study will be used to monitor (check) your health condition as well as any possible effects you might have from taking the study drug. Others will be for PK assessment, the purpose of PK testing is to see how much of the study drug is in your body, and how it is processed by your body over time.

While in the study, you must:

- Come to the clinic for all in-person study visits.
- Let the team know if you take any medication that is not part of the study.
- Take the study drug during the study as directed.
- Record the time and amount of study drug and acetaminophen you use each day using an app called Pins & Needles (tool on your smartphone).
- Wear an actigraphy device on your wrist for one week before each in-person visit. This is to measure activity (for example steps you take).
- Provide urine and blood samples at in-person visits.
- Fill out forms and answer study questions.
- Not drink grapefruit juice or eat grapefruit during the whole study.
- Not use illicit drugs or some medicines which are forbidden in this study (for example, opioids, like Percocet or tramadol. A full list can be provided).

Figure 1: Visit Schedule

| *Visit number* | *V3 (Baseline)* | *V4* | *V5* | *V6* | *V7* | *V8* | *V9* | *V10* |
|---|---|---|---|---|---|---|---|---|
| Timing | Day 0 | V4 has been removed from the study. | Day 7 (+/- 1 day) | Day 28 (+/- 4 days) | Day 56 (+/- 4 days) | Day 84 (+/- 4 days) | Day 91 (+3 days) | Day 114 (+7 days) |
| In-person (I) or remote (R) | I | | I | I | I | I | I | R |

**Study Treatment Period**

You will receive study drug for about 13 weeks (refer to Figure 1). You will need to return to the research site for all visits while you are receiving study drug. The study team will work with you, so the visits are convenient for you. If you cannot attend a scheduled study visit for any reason, please contact the study team to reschedule. A member of the study team will contact you to reschedule the visit. If you are unable to come in for the visit, the study team will contact you or review your medical records to get as much information about your progress.

Every morning during the study, you will take one capsule of the study drug orally (by mouth). The capsule must be taken with food (for instance, at breakfast). The capsule must be swallowed whole with water and should not be chewed, divided, or crushed. You should take the study drug around the same time every day. You will record the time you take study drug each day in the app.

In case you miss taking the study drug in the morning, you can still take it with food up to 12 hours after your planned dose. If more than 12 hours has passed since the planned time, you should skip that dose and take your next dose at your usual time. If you miss a dose, also record this in the app.

***Visit 3 (Baseline, in-person)***

The baseline visit will occur about 2 – 6 weeks after V1 and take about 3 hours. At this visit you will:

- Be asked about any symptoms you are having.
- List any medication(s) that you have taken since the last visit.
- Have a physical exam before you take your first dose of study drug. After taking the first dose of study drug, your vital signs will be measured every 30 minutes for the first 2 hours after taking study drug.
- Have your blood collected (about 3 teaspoons).
- An additional half a teaspoon of blood will be collected for PK.
- Provide a urine sample.
- Pregnancy test. (if applicable)
- Have 5 electrocardiograms (ECG) done. An ECG is a recording of the electrical activity of your heart. The first one is done before you take your first dose of study drug and then every 30 minutes for the first 2 hours after taking that dose. Based on the results of your ECG, about one teaspoon of blood may be taken for your safety each time.
- Be asked questions about your pain and sleep.
- Be asked questions about your mental health. If you are having suicidal thoughts call the study doctor at the telephone number listed on the first page of this form. If you feel in crisis, you can call 911 and/or a Nationwide Suicide Hotline that is answered 24 hours a day with a skilled, trained counselor. One example is the National Suicide Prevention Lifeline at 1-800-273-TALK (8255).
- Have a neurological exam.
- Take your first capsule of study drug in the clinic (with food).
- Get study drug to take every day at home until your next visit.

*Between Visits 3 and 5*

Between the next visit, you will:

- Take study drug once a day
- Answer questions daily on the app
- Submit information daily about taking the study drug and acetaminophen (if you took any) on the app
- Wear actigraphy study device for 1 week, right before the next visit

***Visit 4***

Visit 4 has been removed as part of a protocol amendment version 7.1. All patients will proceed to Visit 5 after completing Visit 3.

**Visit 5 (Early safety check, in person)**

Visit 5 will occur 7 days after Visit 3 (refer to Figure 1). These visits will take about 1 hour. At these visits you will:

- Be asked about any symptoms you are having.
- List any medication(s) that you have taken since the last visit.
- Have your vital signs taken.

- Have an ECG done. Depending on the results, a half a teaspoon of blood may be taken for testing.
- Be asked questions about your mental health.

*Between Visits 3 and 5, 5 and 6, and 6 and 7*

Between the next two visits, you will:

- Take study drug once a day
- Answer questions daily on the app
- Submit information daily about taking the study drug and acetaminophen (if you took any) on the app
- Wear actigraphy study device for 1 week, right before the next visit

***Visits 6 and 7 (follow-up, in-person)***

Visit 6 will occur about 3 weeks after Visit 5. Visit 7 will occur about 4 weeks after Visit 6 (refer to Figure 1). These visits will take about 1 hour. At these visits you will:

- Return the previous study drug bottle and receive a new one.
- Be asked about any symptoms you are having.
- List any medication(s) that you have taken since the last visit.
- Have your vital signs taken, including weight.
- Have a brief physical exam.
- Provide a urine sample.
- Have your blood collected (about 3.5 teaspoons).
- Pregnancy test. (if applicable)
- Have an ECG done
- Have a neurological exam.
- Be asked questions about your pain and sleep.
- Be asked questions about your mental health.

*Between Visits 7 and 8*

Between the next two visits, you will:

- Take study drug once a day
- Answer questions daily on the app
- Submit information daily about taking the study drug and acetaminophen (if you took any) on the app
- Wear actigraphy study device for 1 week, right before the next visit

***Visit 8 (follow-up, in-person)***

Visit 8 will occur about 4 weeks after Visit 7 (refer to Figure 1). This visit will take about 3 hours. At this visit you will:

- Return the previous study drug bottle and receive a new one.

- Be asked about any symptoms you are having.
- List any medication(s) that you have taken since the last visit.
- Have your vital signs taken, including weight.
- Have a brief physical exam.
- Provide a urine sample.
- Have your blood collected (about 3.5 teaspoons).
- Pregnancy test (if applicable)
- If you agree to participate in the future biomarkers study, we will collect another teaspoon of blood to store.
- Have an ECG done.
- Have a neurological exam.
- Be asked questions about your pain and sleep.
- Be asked questions about your mental health.

*Between Visits 8 and 9*

Between the next two visits, you will:

- Take study drug once a day
- Answer questions daily on the app
- Submit information daily about taking the study drug and acetaminophen (if you took any) on the app
- Wear actigraphy study device for 1 week, right before the next visit

***Visit 9 (follow-up, in-person)***

Visit 9 will occur about 1 week after Visit 8 (refer to Figure 1). Before this visit, you will have taken the last dose of study drug. This visit will take about 1 hour. At this visit you will:

- Return the previous study drug bottle.
- Be asked about any symptoms you are having.
- List any medication(s) that you have taken since the last visit.
- Have your vital signs taken, including weight.
- Have a brief physical exam.
- Provide a urine sample.
- Have your blood collected (about 3 teaspoons).
- Have an ECG done.
- Be asked questions about your pain and sleep.
- Be asked questions about your mental health.
- Return the actigraphy device and smartphone (if provided).

***Visit 10 (Final Safety check, remote)***

Visit 10 will occur about 3 weeks after Visit 9 (refer to Figure 1). You do not need to come to the study site for this visit. A member of the study team will call you to ask how you have been doing since taking the last dose of study drug. After this call, your participation in the study is complete.

***Unscheduled Visits***

If you experience side effects, the study doctor may ask to you come for an additional visit at any time during the study. This is to check your health. Sometimes, this visit must happen within one week (or less if the study doctor thinks it's important for you to return sooner) of your last visit. The study doctor will decide which study activities will happen. At each of these visits, you will also be asked questions about your mental health.

After Study Treatment:

Because this is research, the study drug will be given to you only during the study. It is not available after the study is over. The study team will discuss what pain medications you can start taking again. They may also refer you back to your doctor to manage your pain after the study has ended.

## WHAT IS EXPECTED OF YOU IF YOU TAKE PART IN THIS STUDY?

If you join this study, you will be expected to:

- Stop all treatments you are currently taking for your pain, including pills, creams, patches, marijuana, cannabidiol (CBD) oil, etc. While you are in this study, you can only take acetaminophen for pain. A maximum of 3 grams (6 pills of 500 mg each) per day can be taken. Acetaminophen is not provided by the study.
- Come to the clinic for all in-person study visits. Visits will be scheduled at your convenience as best as possible. If you need to miss a scheduled appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment. Study staff may contact you by telephone or telemedicine to obtain information missed at an in-person study visit. On the day of your visit:
    - Bring all study drug bottles (including empty bottles) with you each time you visit the study site. This is so the study team can confirm the amount you reported taking since your last visit.
    - Let the study team know if you take any medication that is not part of the study. At each in-person visit, you will be asked about changes to your medications. You should provide the study team with any new medications or changes to existing medications.
    - Have the information of any changes in your health you have experienced since the last visit (headache, hospitalization etc.).
- Take the study drug during the study as directed.
    - You must take the study drug every day for about 13 weeks.
    - You will take the study drug every morning orally (by mouth) with food. You should take the study drug around the same time every day.
    - Record the time you take the study drug in the app every day.
    - In case you miss taking the study drug in the morning, you can still take it with food up to 12 hours after your planned dose.

  - You will be given your study drug in childproof packaging. You should keep it in a safe place out of sight and reach from children and animals. Make sure no one else uses your study drug.
  - Keep the study drug at room temperature.
- Record the time and amount of study drug and acetaminophen you use each day using the app.
  - This is to keep track of the study drug you are taking each day. You will get a reminder from the app when it is time to take your study drug. These will help remind you how important it is to take your study drug and record your acetaminophen use.
- Wear the actigraphy device on your wrist. You will need to wear the device for the week leading up to your next clinic visit. The app will remind you when it is time to put the device on.
- Provide urine and blood samples at certain times during the study.
- Provide a stool sample if you agree to have your samples stored for future research.
- Fill out forms and answer study questions. This will include daily questions about your pain and sleep. Please complete these as instructed on the app.
- Not drink grapefruit juice or eat grapefruit during the whole study.
- Not use illicit drugs or some medicines which are forbidden in this study (for example, opioids). You can discuss with your study doctor which medicines are not allowed. Urine drug tests will be done at every visit.
- **If you want to participate in any other research study, you are expected to discuss it with the study staff first.** Talking to the study team can help protect you from possible injury due to side effects of combining study drugs.
- **You cannot participate in this study if you are pregnant or able to become pregnant.** There have been no studies about the effect of the study drug on embryos or fetuses.

## RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

### RISKS OF STUDY DRUGS

Study drugs may cause all, some, or none of the risks or side effects listed.

### NRD135S.E1

To date, 114 people have received NRD135S.E1. Of those, 49 (43%) were healthy participants and 65 (57%) were participants with your disease, PDPN. Participants with PDPN have tolerated the study drug well at doses comparable to the one you would take in this study.

Healthy participants treated with the study drug had side effects such as:
- Headache
- An increase in blood pressure
- A change in their heart rate

Each reported in more than 10% of participants. They also experienced anxiety or weakness (reported in less than 10% of participants).

PDPN participants treated with the study drug had side effects such as:

- Headache (reported by 12.3% of participants)
- Cough (reported by 3% of participants)
- Weakness (reported by 1.5% of participants)

Most of the side effects were mild and none were severe. Headache was the only side effect considered related to the study drug.

### Placebo

Participants in this study may receive a placebo. Taking a placebo is the same as not taking any active drug. If you receive placebo, your pain associated with diabetes may get worse, stay the same, or improve, just as it may have done without any treatment. However, during the whole duration of the study, you will be allowed to use up to 3 grams of acetaminophen per day (6 pills of 500 mg each).

## RISKS OF STUDY PROCEDURES

### Blood Draws

Drawing blood may cause pain or bruising where the needle goes into your body. Very rarely, people may become light-headed or faint. Before your blood draw, tell the person drawing your blood if you think you might get dizzy, lightheaded, or faint.

### ECG

Skin irritation is rare but could happen during an ECG from the electrodes or gel that is used.

### Answering Questions

Some of the questions we will ask you may make you feel uncomfortable. You may choose not to answer any question at any time and for any reason.

### Mobile App

As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study doctor. While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor,

institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

**Other Pain Treatments**

If you are using any treatment for your pain, you will be asked to stop taking it during the study. This can be any pills, creams, shots, oils, etc. You may be asked to wait before starting the study to make sure these treatments have completely left your body. During this time, your symptoms may not get better or may get worse. If your symptoms get worse, tell the study doctor immediately.

You will be allowed to take 3 grams of acetaminophen day (6 pills of 500 mg each) if your pain is unacceptable. You should discuss the allowed dose with the study doctor.

**Other Study Procedures**

There is always a chance that any study activity can harm you. There is also a chance you may experience a risk or side effect we did not know about from other studies.

There are possible risks related to the clinical care you would normally get. Risks that are a part of normal clinical care are not included in this form. You should talk with your health care providers if you have any questions about the risks of normal clinical care.

**UNFORESEEN RISKS**

Since the study drug is experimental, there may be other unknown risks. The study doctor will tell you if there is a new risk that may change whether you want to stay in the study.

All medicines have the potential risk of an allergic reaction, which if not treated right away, could become life threatening. You should seek medical help right away if you think you have any of the following symptoms of a serious allergic reaction:

- Trouble breathing and/or swelling of the face, mouth, lips, gums, tongue, or neck.
- Rash
- Hives
- Blisters

It is important that you tell the study doctor about any changes in your health as soon as they occur, whether or not you think they are caused by the study drug.

**REPRODUCTIVE RISKS**

Since the study drug is experimental, the risks to an embryo, fetus, or nursing infant are unknown. Therefore, you cannot join this study if you can become pregnant.

**Females**

Females who are either 1 year past menopause, surgically sterile, or have certain medical conditions that prevent pregnancy are not considered capable of having children. If you are a female, a urine test will be done at screening and at visit 9 to confirm you are not pregnant. If

you become pregnant, you will be withdrawn from the study immediately, and the study staff will collect information about the pregnancy, its outcome, and the health of the child after birth.

## NEW FINDINGS

While you're in the study, the study team will let you know if there are any new findings that may change your mind about participating. You may also contact your study doctor at any time after your study participation ends to find out if any new information has become available.

## BENEFITS

You may experience pain relief while participating in the study. However, there is no guarantee that your pain will improve. Your response to the study drug may give doctors more information about treating pain in people with PDPN. This knowledge could benefit other patients in the future.

## COMPENSATION FOR PARTICIPATION

«Compensation»

You will be compensated up to $65.00 for each completed study visit and up to $20.00 for completion of associated forms.

**Compensation for Transportation:**
You will be provided compensation/reimbursement of up to $100 at each visit to cover the expenses associated with traveling to and from in-person study visits, such as public transit or parking fees.

**Compensation for Dependent Care:**
Understanding that study participation may require arrangements for dependent care, you will be provided compensation/reimbursement of up to $100 at each visit to support you in securing appropriate care for your dependents during your engagement in study visits.

**Compensation for Meals:**
You will be provided compensation of up to $10 to support/cover the cost of meals provided by the site as (snacks/meal voucher/meal/etc.).

If you do not complete the study, for any reason, you will be compensated for each study visit you do complete. The compensation will be provided to you (in a check/via prepaid card/etc.) upon completion of each study visit or milestone as outlined in the study schedule.

If you have any questions regarding your compensation for participation, please contact the study staff.

## WHAT HAPPENS IF I AM INJURED AS A RESULT OF TAKING PART IN THIS RESEARCH STUDY?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may still be responsible for some of them. For example, if the care is billed to your insurer, you

will be responsible for payment of any deductibles and co-payments required by your insurer. To ask questions about this, talk to the study doctor or study staff.

Injuries sometimes happen even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing and dating this form. If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed on the first page of this consent form.

## WHAT WILL I HAVE TO PAY FOR IF I TAKE PART IN THIS STUDY?

Study funds will pay for certain study-related items and services that are being done only for research. However, we may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care.

If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs. **Before you agree to be in this study, you should contact your health insurer to see if your plan will cover the costs required as part of your participation.**

## WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor’s or study site’s decision to exclude you from participation;
- Results of tests and/or procedures;

**Please contact the study doctor 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, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00063849.

## VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate. You may withdraw from the study for any reason. If you leave the study, there will be no penalty or loss of benefits to which you are otherwise entitled. Leaving the study will not have any effect on your future medical care. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you.
- If you fail to follow directions for participating in the study.
- If it is discovered that you do not meet the study requirements.
- If the study is canceled; or
- For administrative reasons.

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

## INFORMED CONSENT

### Statement of Person Giving Informed Consent

- I have read, listened to an audio recording or received a verbal explanation of this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.
- By signing and dating this form, I do not give up any of my legal rights.
- I will get a signed and dated copy of this consent form.

### SIGNATURE BLOCK FOR PARTICIPANT:

I give my consent to take part in this research study.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date/Time

### SIGNATURE BLOCK FOR WITNESS LINE (if applicable):

My signature below documents that the information in the consent document and any other written information was accurately explained to the participant. I have witnessed the voluntary consent of the participant, for their involvement in the study.

_____
Printed name of the Impartial Witness

_____ _____
Signature of the Impartial Witness Date/Time

### Statement of Study Doctor or Person Obtaining Consent:

- I have explained the research to the study participant.
- I have answered all questions about this research study to the best of my ability.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date/Time