# SCREENING INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

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|---|---|
| **Sponsor / Study Title:** | **Massachusetts General Hospital, CTNI / "Platform Protocol to Assess Treatments for Painful Diabetic Peripheral Neuropathy"** |
| **Protocol Number:** | **EN21-PP** |
| **Principal Investigator: (Study Doctor)** | **«PiFullName»** |
| **Telephone:** | **«IcfPhoneNumber»** |
| **Address:** | **«PiLocations»** |

## KEY INFORMATION ABOUT THIS STUDY

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 nerve pain called peripheral neuropathy because of your diabetes. 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).

**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.

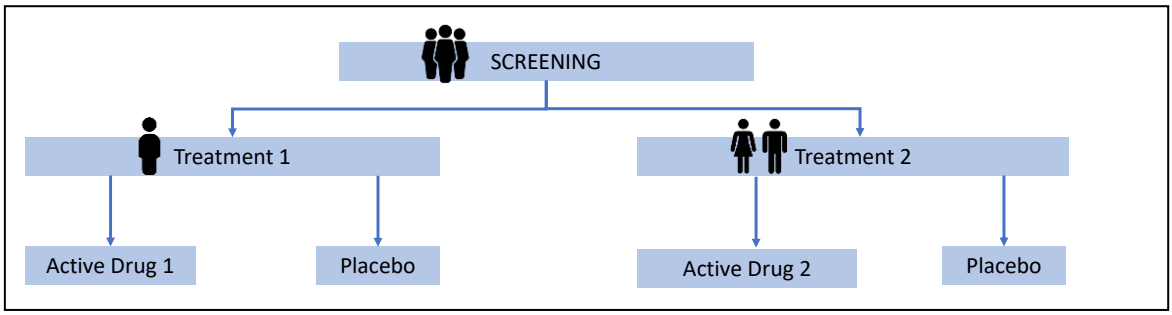
## WHAT IS THE PLATFORM PROTOCOL TO ASSESS TREATMENTS FOR PAINFUL DIABETIC PERIPHERAL NEUROPATHY?

A Platform Protocol (PP) is a special type of study that looks at multiple different study treatments for people with the same diagnosis. This PP is for people that have painful diabetic peripheral neuropathy (PDPN), also known as diabetic neuropathy.

This PP will have multiple study treatments that may be studied at the same time. Because this is a PP, different people in this study may be prescribed different study treatment(s) and/or dosage(s). For safety reasons, not every study treatment is a good fit for every person. Each study treatment has its own specific requirements. If you join the study, you will be assigned to a study treatment based on whether you meet specific requirements. If you are eligible for more than one, you will be randomly assigned to one, like rolling a dice. If you decide you do not want to participate in the study treatment you have been assigned to, your participation in the PP will end.

Once you are assigned to a study treatment, you have an equal chance (like flipping a coin), of being assigned to the active study treatment or placebo. A placebo is a pill or cream that looks like an active study treatment but does not contain any drug. Neither you, the study doctor, nor any of the study staff will know whether you will receive active study treatment or placebo. However, your study doctor can find out in case of an emergency.

*Figure 1: Platform Protocol Design*




## WHY IS THIS RESEARCH STUDY BEING DONE?

We are doing this research to find out if different treatments have an effect on painful neuropathy due to diabetes. We also want to find out if these treatments are safe to take without causing too many side effects.

We don't have a set number of participants that we will enroll in the overall Platform Protocol or at the study site. The Platform Protocol has no fixed end date. This is because more study treatments will be added as time goes on and there will be more study treatments to test.

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

Participation in some study treatments may take longer than others. The length of each study is described in the study treatment specific consent forms. However, you can expect your participation to last up to 23 weeks.

## 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 which new experimental pain treatments help people with PDPN.

- Some study treatments will require that you discontinue your pain medications including pills, creams, patches, marijuana, cannabidiol (CBD) oil, etc.
- You may need to take time from work or other responsibilities for study visits and procedures.
- Your pain could worsen while participating.
- If you are of childbearing potential (can get pregnant) you will be asked to use two forms of birth control.
- You will not be able to choose which specific study you are assigned to. If, after you read or listen about that study, you decide not to participate, you will no longer be able to participate in the platform study overall.
- You will be compensated for your time and other possible costs related to attending study visits (childcare or travel, if applicable).

The sections below describe the platform study completely should you decide to participate. If you decide to participate, you will be asked to sign a separate informed consent form for the specific study to which you are assigned. The risks of the study drug(s) in that study, and of any additional procedures will be described in that consent form.

## 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 OTHER TREATMENTS ARE AVAILABLE FOR MY CONDITION?

You do not have to be in this study to be treated for your PDPN. There are other options for treatment that are available over the counter or prescribed by your doctor. Current treatment therapies for PDPN include:

- Duloxetine (Cymbalta)
- Pregabalin (Lyrica)
- Tapentadol (Nucynta)
- A high-dose capsaicin patch (Qutenza)

Please talk to the study doctor about your treatment options before you decide if you will take part 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 this consent form. No study procedures will be performed until this consent form is signed and dated.

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 other pain medication you use each day using an app.
- Wear an actigraphy device on your wrist for one week before each in-person visit. This is to measure activity (for example steps).
- Provide urine and blood samples at in-person visits.
- Fill out forms and answer study questions.
- Not use illicit drugs or some medicines which are forbidden in this study (for example, opioids like Percocet or Tramadol).

*Figure 2: Visit Schedule*

| *Visit number* | *Daily reporting* | *V1 (Screening)* | *V2 (Screening)* |
|---|---|---|---|
| Timing | Daily | Single Day Between Days -45 to -14 | Period of time between Days -44 to -1 |
| In-person (I) or remote (R) | R | I | R |

*Additional study treatment specific visits will be described in the study treatment specific consent forms.

### Screening

***Visit 1 (in-person)***

After you sign and date this form, the study team will start the study activities. They will conduct the following activities to see if you meet the requirements for this study. If you do not meet the requirements, the study doctor will tell you why. These procedures are expected to take between 2-3 hours for you to complete.

- The study doctor will review your medical and surgical records.
- You will be asked questions about your health. The study team will need to know about your health now and in the past. They will ask you about your physical and mental health. They will ask you about past and current medications you have taken.

- You will have a physical exam to make sure you are generally healthy. It will include testing your blood pressure, pulse, breathing rate, temperature, height, and weight.
- You will also have a neurological exam. This exam will include measurements of your muscle strength, reflexes, and sensations.
- You will have your blood drawn (about 3 teaspoons) for standard laboratory tests. These blood tests will check how well your liver, kidney, and thyroid are functioning. These tests will also look for underlying conditions that may cause or contribute to your PDPN. The tests will also show the levels of sugar and cholesterol in your blood. These values and the blood counts will be used to ensure your diabetes is currently stable.
- You will be asked to provide a urine sample. This sample will be used for standard laboratory tests to measure your health. The sample will also be used to test for substances of abuse.
    - A urine pregnancy test will also be done when applicable.
- You will be asked to have an electrocardiogram (ECG). An ECG is a recording of the electrical activity of your heart.
- You will be asked to answer questions about any current and past substances you may have used. You will also be asked about whether you have been treated for substance use disorder.
- You will be asked questions about your mental health and whether you have had thoughts about or have taken steps to hurt yourself. 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).
- You will be asked about your pain.
- You will be given the option to join a future biomarkers study. Biomarkers are information found in blood that give scientists information about the disease. They also give information about how the body uses drugs. If you agree, your samples will be stored at NYU's Center for Biospecimen Research and Development (CBRD). The samples will be analyzed in the future. You do not need to agree to the future biomarkers study to participate in the main study.
    - If you agree to participate, we will collect additional blood (about another 4 teaspoons) to store for future studies. We will also send you home with a stool collection kit and instructions on how to return the sample to us.

**If you are eligible to continue, the study team will:**

- With your permission, download the smartphone app, called "Pins & Needles", on your phone. The Pins & Needles app is used to let you securely answer questions about the study from your phone. If you do not have a smartphone (or a compatible phone), we will provide you with one to use through your study participation. Pins & Needles is also accessible on a laptop or desktop computer.
- Explain how to answer daily surveys and record when you take the study drug/ acetaminophen (commonly known as Tylenol) in the app. You will get alerts from the app when it is time to do something. To be part of this study, you must answer these questions each time you receive an alert. The study team will train you how.
- Provide you with an actigraphy device (counts steps and measures sleep). You will be given instructions on how to use it during the study. You will be asked to wear the device on your wrist. You only need to wear the device for the 7 days before your next in-person visit.

***Visit 2 (remote)***

For about 2 – 6 weeks (refer to Figure 2):

- You will answer questions about your pain and sleep in the Pins & Needles app every day.
- Record how much acetaminophen you took, if any, daily in the app.

A member of the study team will call to:

- Ask how you are feeling
- Ask about any medications you are taking
- Discuss the study tests, procedures, and requirements, and any special instructions
    - For example, you may need to stop taking your current pain medications or answer additional questionnaires. Acetaminophen is the only pain medicine allowed in this study, other than the study drug.

The study doctor will review the results of your tests and your questionnaire responses, and will use that information to determine whether you can participate in the study. If you meet the requirements, we will:

- Schedule your next visit to our clinic
- Give you the consent form for the study treatment you were assigned to. We ask that you review this new consent form before the next clinic visit. You will be required to sign and date that consent form before your participation begins in that study.

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

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

- Come to the clinic for all in-person study visits per this consent and the study treatment specific consents. 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.
- 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.
- Record the time and amount of study drug and other pain medicine you use each day using the app.
    - This is to keep track of the drugs you are taking each day. You will get a reminder from the Pins & Needles 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 daily pain medication use.
- Bring all study drug (including empty packages, if applicable) 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 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.

- Participate in study activities, as described by the study treatment arm.
- 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 use illicit drugs or some medicines which are forbidden in this study (for example, opioids like Percocet or Tramadol). You can discuss with your study doctor which medicines are not allowed. Urine drug tests will be done at every visit.
- Use the study drug during the study as directed. You should keep it in a safe place out of sight and reach from children and animals.
- **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 drugs.
- **You should not participate in this study if you are pregnant.** If you are pregnant, plan to become pregnant, or are nursing (breastfeeding), you cannot participate in this study. If you can become pregnant, you may not be eligible for all the study treatment arms.
    a. If you can become pregnant, you must practice an effective form of two types of birth control, which are defined as those, alone or in combination, that result in a low failure rate (for example, less than 1% per year) when used consistently and correctly. This must be done before, throughout, and for 30 days after the last dose of study drug.
    b. Specific requirements for male participants (regarding contraception) are described in each study specific consent.

    - Before participating in this study, you must take a urine pregnancy test.
    - You may need to take additional pregnancy tests depending on the study treatment arm you are assigned to.
    - You should notify the study team immediately if there is a chance you might be pregnant.
    - The study team will also ask you about your birth control method(s) at each visit. You should let the team know if you stopped using your birth control method(s), even if only for a short period of time.

## RISKS, SIDE EFFECTS, AND/OR DISCOMFORTS

### Washout

If you are using any medication for your pain, you may be asked to stop taking it during the study. This will depend on the medication you are taking, and the study treatment arm you are eligible for. This can be any pills, creams, patches, marijuana, cannabidiol (CBD) oil, 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 specific types of pain medication at specific doses if your pain is unacceptable (3 g of Tylenol per day, a total of six 500 mg tablets). You should discuss the allowed dose with the study doctor. These medications and doses differ for each study treatment arm.

### 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 (sticky patches) 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 Study Procedures

There is always a chance that any study activity can harm you. The procedures in this study are no different. 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.

## REPRODUCTIVE RISKS

Many of the treatments included in this study are experimental (not yet approved by the FDA). The risks to an embryo, fetus, or nursing infant are unknown. Therefore, if you are pregnant, planning to have a child, or are breastfeeding, you cannot join this study.

### Females

You must avoid becoming pregnant while in the study to prevent any known risks. All women who can get pregnant must have a negative urine pregnancy test before participation and must use a medically acceptable method of birth control before, throughout, and for 30 days after the last dose of study drug.

The study doctor will discuss acceptable birth control methods with you.

Acceptable methods of birth control for use in this study are:

- Hormonal methods such as oral birth control pills, implantable (for example, Nexplanon), injectable (for example, Depo-Provera), or transdermal contraceptives (for example, the patch) for a minimum of 1 full cycle (based on your usual menstrual cycle period) before starting the study drug;
- Total abstinence from heterosexual intercourse since your last period before study drug administration;
- Vaginal ring
- Intrauterine device (IUD); and/or
- Double barrier method (condoms, sponge, or diaphragm with spermicidal jellies or cream).

Women using hormonal methods must follow the product package insert instructions about additional protection at times when doses may be missed.

Rhythm, withdrawal, and single barrier are **NOT** acceptable methods of contraception.

If you become pregnant while you are participating in this study, tell your study doctor right away. The study drug will be stopped and you will be withdrawn from the study immediately. The study staff will collect information about the pregnancy, its outcome, and the health of the child after birth.

Women who are either 1 year past menopause or surgically sterile are not considered capable of having children.

### Males:

Specific requirements for male participants are described in each study treatment specific consent form.

## 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 people 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.

## CONFIDENTIALITY

Your study information will be identified with a code so that the study results are not linked to your name. Data from the electronic questionnaires and this electronic Informed Consent Form will be collected using secure electronic systems. These systems are fully compliant with all applicable regulations, including 21 CFR Part 11 and HIPAA. These steps help to make sure your data is protected.

Strict operating procedures are enforced to protect the confidentiality, integrity, and access to your protected health information (PHI). These procedures cover how the data is stored, transmitted, and maintained. Your PHI will ONLY be accessible to designated staff and select, approved members of the study team. This includes people who review the data to make sure the study is being done correctly. Those who work to protect participant data and safety will

have access to your data. Those responsible for leading and organizing the study will also have access to your data. These groups will only view your data as necessary to ensure participant safety and the integrity of the study.

You will be sent multiple automated text message reminders from the “Pins & Needles” app. These notifications will help remind you to complete study activities. Notifications will remind you to answer questionnaires and report how much pain medication you took that day. You will also be reminded when to put on your actigraphy study device.

Records of your participation in this study will be kept confidential, except when sharing the information is required by law or as described in this form. The study doctor, the sponsor, or persons working on behalf of the sponsor will be able to inspect and copy confidential study-related records which identify you by name. Under certain circumstances, the United States Food and Drug Administration (FDA), National Institutes of Health (NIH), and the Institutional Review Board (IRB) will also have access. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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.

### *Certificate of Confidentiality*

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may permit them to release information to insurers, medical providers, or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your information.

### *Sharing Data with a National Repository*

Because this study is paid for by the NIH, the data must be shared with a national data repository. Sharing data with the national repository means your data can be shared with other researchers, without giving identifying information about you. None of your identifiable

information can be shared with the national data repository. To share data that cannot identify you, the study team will create a special number for you, known as a Global Unique Identifier (GUID). They will use your personal information, like your name and date of birth, to create the GUID. Once created, only the study team will know which GUID belongs to you.

### 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. **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.**

## AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If I take part in this research study, how will you protect my privacy?

Federal law requires the study doctor and study team to protect the privacy of health information and related information that identifies you. We refer to this information as “identifiable information.” In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- The Clinical Coordinating Center (CCC) at Massachusetts General Hospital (the sponsors of this study), and people or groups it hires to help perform this research or to audit the research
- The Data Coordinating Center (DCC) at New York University – Langone Health, their representatives, and individuals with oversight of the DCC.
- Researchers and staff involved in this study at this study site
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research (Advarra Institutional Review Board)
- A group that oversees the data (study information) and safety of this study
- Non-research staff at this study site who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration (FDA), the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect

your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside this study site, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

## Your Privacy Rights

You have the right not to sign and date this form that allows us to use and share your identifiable information for research; however, if you don't sign and date it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing at the address listed on the first page of this form. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study, listed on page 1 of this form. You may only get such information after the research is finished.

## STATEMENT OF AUTHORIZATION

I have read, listened to an audio recording, or received a verbal explanation of 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/Time

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

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

_____
Printed name of the Impartial Witness

_____ _____
Signature of the Impartial Witness Date/Time

### FUTURE RESEARCH STUDIES

Some of your data from this study may be kept for future use. If this happens, any of your identifying information will be removed. This data could then be used for future research studies or distributed to another study doctor. The future study team will not know who you are or have access to your identifying information. You will not be notified of the use of your data in any future studies.

Later in this form, you will be asked if you consent to future research on your biological samples. Having your samples stored and analyzed for future research is not required to participate in this study.

## 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.

## PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to have my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

❒**YES** (If yes, please complete the information below)
❒**NO**

| | |
|---|---|
| Name and address of family doctor or primary health care provider: | Name: |
| | Address: |
| | |
| Telephone and Fax Number: | Tel: |
| | Fax: |

## APP REMINDER NOTIFICATIONS

I consent to get push notifications about at-home study activities, like reminders to answer questions in the app.

❒**YES**
❒**NO** (If no, unable to participate in study)

## Informed Consent

### Statement of Person Giving Informed Consent and Authorization

- 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 and agree to allow my health information to be used and shared as described above.

_____
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

## CONSENT FOR FUTURE RESEARCH STORAGE AND SHARING OF MY BIOLOGICAL SAMPLES:

Taking part in having your biological samples collected and used for future research is voluntary. If you would like to participate in this part of the study, please sign the consent below.

### If You Choose to Have Your Samples Stored and Used for Future Research

You have the option to have your whole blood, plasma, and stool samples stored securely at the Center for Biospecimen Research and Development (CBRD) NYU Langone Medical Center. You may choose not to provide your samples for future research.

If you choose to have your samples used for future research your samples will be stored indefinitely. Your samples could be used for research into any type of disease. We will do our best to protect your personal information. Your name and other personally identifying information will not be kept with the samples. Your samples will either be stored without a code linking them to you or they will have a code that links to your identifying information. If your data has a code, the key to the code will be kept at the study site in a separate, secure area and will not be shared outside of the study site.

Collecting your samples for future research is part of the NIH HEAL Initiative focused on understanding and developing new treatments for addiction and pain. Research gives us the best information and progresses more quickly when data is available from many studies and many individuals, and when many researchers can work with the samples and analyze them in different ways. Therefore, your samples will be used for this and other NIH HEAL Initiative studies. Your stored samples will also be made widely available to other researchers. The shared samples may be used indefinitely for research not related to this study or the HEAL Initiative, without asking you for additional consent.

Your samples collected for this study contain your DNA. (deoxyribonucleic acid is the material inside the nucleus of cells that carries genetic information). DNA can be thought of as a “cookbook” that contains the recipe of your body. Your DNA and genetic information are unique to you. Your genetic information may also be used for research unrelated to this study.

If you withdraw from this research study before it is over, we will keep and continue to use samples that have already been collected.

Because all samples and data are de-identified, no results will be returned to research participants

### Potential benefits of sharing of samples

There is no direct benefit to you from the storage and sharing of your samples, but sharing may help researchers learn more about PDPN and other diseases, which may help you or others in the future.

### Risks of sharing samples

Even though we will protect your privacy as much as possible, there is a very small chance that the samples could be identified as yours. The risk of this happening is very small but may increase in the future as technology changes.

Research using samples from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your samples and data.

## GENETIC INFORMATION

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

## BIOLOGICAL SAMPLE CONSENT

I have read, listened to an audio recording or received a verbal explanation and understood the information for collecting samples. I have had an opportunity to ask questions and all my questions have been answered to my satisfaction. I voluntarily agree to participate in having my samples stored and used for future research until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

**Signature of Participant:**

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Yes: _____ No: _____

_____
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