the PERIPHERAL NEUROPATHY | Research Registry

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the mission

The Foundation *for* Peripheral Neuropathy (FPN or "the Foundation") is a 501(c)(3) nonprofit organization dedicated to improving the quality of life for those living with Peripheral Neuropathy (PN). FPN has a deep commitment to promoting and supporting research that would lead to better diagnosis, treatment and eventually a cure for Peripheral Neuropathy. Before we can move forward to improved treatments and a cure, we must have a better understanding of Peripheral Neuropathy.

What is Peripheral Neuropathy?

PN occurs when peripheral nerves are damaged or destroyed and can't send messages from the brain and spinal cord to the muscles, skin and other parts of the body which can cause debilitating symptoms. An estimated 30 million Americans and millions more worldwide are affected by PN.

In order to achieve its mission, the Foundation initiated the creation of the Peripheral Neuropathy Research Registry (PNRR) by assembling a team of leading experts from Johns Hopkins University, Northwestern University, Icahn School of Medicine at Mount Sinai Medical Center, University of Utah, Kansas University Medical Center, Washington University School of Medicine in St. Louis and University of Michigan as consortium members.

The PNRR, a national registry, has been created to help researchers learn more about Peripheral Neuropathy and to characterize the phenotypes (clinical features) and genotype (genetic makeup) of patients with the disorder. The registry will facilitate both the basic and clinical research studies needed for an improved understanding of the causes and development of PN.

The Registry is a standardized collection of data and DNA samples on individuals diagnosed with Diabetic Peripheral Neuropathy (DPN), Chemotherapy-Induced Peripheral Neuropathy (CIPN), Idiopathic Neuropathy and HIV/AIDS associated neuropathy. It will include detailed information about their medical, genetic, social and family history and the information will be stored in an anonymized dataset.

DNA sequencing

…led by a
consortium of experts…

WHY IS THE PERIPHERAL NEUROPATHY RESEARCH REGISTRY NEEDED?

PN is a complex and still not fully understood disorder. At present there is no standardized protocol for the diagnosis and evaluation of PN patients, so people are evaluated in many different ways.

The primary goal of having a centralized repository of standardized information on PN patients is to provide qualified researchers with detailed information about large numbers of uniformly evaluated patients, and reduce variability in clinical studies and research. The PNRR will allow for various types of research, education, and outcome improvement initiatives. The key objectives of the registry are to:

- **Understand the disease**
- **Improve diagnosis of Peripheral Neuropathy**
- **Develop new effective treatments**
- **Disseminate knowledge to researchers and clinicians**
- **Find a cure for Peripheral Neuropathy**

When you participate, you contribute to the larger picture by:

- **Actively contributing to a greater understanding and research into your disease**
- **Adding to improved diagnosis and clinical care**
- **Connecting patients and families to researchers**
- **Providing data for pre-clinical and clinical research**
- **Helping to improve the lives of PN patients**
- **Allowing study of the natural history of Peripheral Neuropathy**
- **Helping researchers lay the foundation for the development of new treatments, diagnosis, prevention and eventually a cure for PN**
- **Providing access to data for pharmaceutical and biotechnology companies to guide the discovery of new diagnoses and treatments, clinical trial design and patient recruitment**
- **Receiving personalized health information about new or promising treatments, and opportunities to participate in clinical trials**

WHO MANAGES THE PNRR?

The Registry operates under the direction of *the* Foundation *for* Peripheral Neuropathy and is guided by the PNRR Scientific Committee comprised of leaders in the medical, ethical, scientific and PN communities. All data and samples are securely held at Indiana University in Indianapolis, Indiana.

WHO IS ELIGIBLE TO ENROLL?

Participation in the Registry is voluntary. The decision not to participate will not affect your medical care in any way. Individuals over the age of 18 who have been diagnosed with Diabetic Peripheral Neuropathy (DPN), Chemo-induced Peripheral Neuropathy (CIPN), Idiopathic Peripheral Neuropathy and HIV/AIDS associated neuropathy are eligible to enroll. If you are not currently a patient at one of the Consortium sites listed on the back of this brochure, but you are interested in participating, please contact the research coordinator nearest to you. Neuropathy patients currently being seen at one of the participating consortium sites interested in enrolling in the Registry can contact their research coordinator to discuss enrollment.

WHAT ARE PARTICIPANTS ASKED TO DO?

- **Review and Sign the Informed Consent Form—**You will be asked to complete the PNRR informed consent document in order to participate in the registry. This document provides the medical center and medical research team permission to enroll you in the registry.

- **Complete the Patient History Questionnaire—**The *PNRR Patient History Questionnaire* will ask questions about your medical and family history.
- **Complete Annual Follow-up Questionnaires—**About once a year, you may be contacted for follow-up information to ensure their information stays up to date.
- **Donate a biological sample—**You will be asked to donate a blood sample.

HOW MANY TIMES MUST I BE SEEN BY THE PHYSICIAN?

You must be willing to be seen by a neurologist at one of the participating consortium sites at least once.

WHAT HAPPENS AFTER I COMPLETE MY FORMS?

Once you have consented to participate in the registry your patient history questionnaire will be reviewed by the research coordinator and/or your physician. During your examination, your physician will complete a physician form on your neurological and physical examinations. If required, you will be asked to sign a separate consent form to release medical records pertaining to you. Your patient history information and information obtained from your neurological and physical examinations will be entered and stored in the registry. You are free to decline or withdraw participation at any time.

HOW IS MY PERSONAL INFORMATION PROTECTED?

Once your information is entered into the registry, it is de-identified. The information you and other participants provide will be shared with researchers, scientists, and/or pharmaceutical companies who are conducting research studies. Your personal information will be stored in a secured database. Only the individual research coordinators and researchers at the participating consortium sites will have access to the database. Third parties will not be given direct access to the database. Requested data for research studies will be extracted from the database and then sent to third parties. Your name will never be used without your permission. If any researcher wants to invite you into a research study for which additional information will be collected, the research coordinator at the participating consortium site will contact you first.

HOW CONFIDENTIAL IS THIS DATABASE?

In all respects, confidentiality about patients will be strictly maintained. The database is stored at Indiana University, in the department of Medical and Molecular Genetics located in Indianapolis, Indiana. The group has 30 years of experience in maintaining very large registries, and they have a state-of-the-art security system with many safeguards in place to maintain patient confidentiality. They have received qualified accreditation from the Association of Accreditation of Human Research Protection Program Inc.

AAHRPP
Association for the Accreditation of Human Research Protection Programs, Inc.®

HOW IS RESEARCH CONDUCTED?

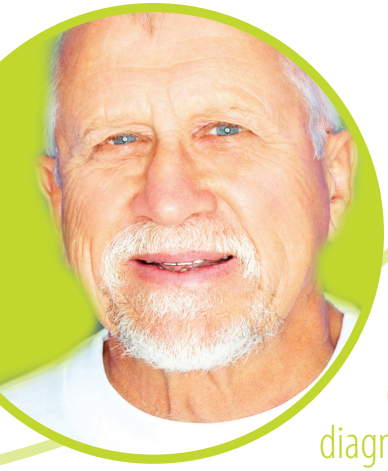
De-identified data and samples from participating consortium sites are aggregated into the registry. PNRR dissemination procedures for the purpose of providing clinical data and biological specimens to investigators for basic and clinical research requires the researcher to submit a research proposal to the Foundation describing the project which represents cutting-edge studies that will potentially move the research field forward or have a high impact on prevention and/or effective new treatments for PN. The Foundation will submit all proposals to their PNRR Scientific Advisory Committee to review and approve prior to any dissemination of clinical information or biological specimens to researchers.

CLINICAL TRIAL AND STUDY RECRUITMENT

For a list of clinical trials pertaining to Peripheral Neuropathy, please visit the Foundation's website at www.foundation-forpn.org. If you have any questions about a specific clinical trial or study, please contact *the* Foundation *for* Peripheral Neuropathy at 847-883-9942 and we would be happy to help you.

CAN I RECEIVE INFORMATION ABOUT THE PROGRESS OF THE PNRR, FUTURE CLINICAL TRIALS OR *THE* FOUNDATION *FOR* PERIPHERAL NEUROPATHY?

Yes, for more information about the Foundation's research and progress to date, please visit our website at www.foundationforpn.org.



the ultimate goal is improved diagnosis, treatments, prevention and possibly a cure

For more information on enrollment, contact the nearest participating consortium site.

Johns Hopkins University
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Fax: 410-502-5459

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Research Study Coordinator
Peripheral Neuropathy Clinic
675 North St. Clair St., Suite 20-100
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Phone: 312-503-6968
Fax: 312-908-5073

Icahn School of Medicine at Mount Sinai
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