the Foundation *for* Peripheral Neuropathy

Registry Data Use Policy

Overview

In 2008, *the* Foundation *for* Peripheral Neuropathy ("Foundation") initiated the development of the Peripheral Neuropathy Research Registry ("PNRR"), currently maintained by the Department of Medical and Molecular Genetics at Indiana University School of Medicine ("Indiana University"). The PNRR consortium was created to foster bold and innovative partnerships that bring together some of the best scientific and clinical talent in a strategic effort to promote collaborative multi-institutional research.

Peripheral neuropathy is the manifestation of many different conditions that can damage the peripheral nerves and is considered a neurological disorder rather than one distinct disease. PNRR is focusing on painful neuropathies, often considered the most debilitating. Painful neuropathies include diabetic, idiopathic, chemotherapy-induced and HIV/AIDS peripheral neuropathies.

While limited treatment options are available that mitigate some of the symptoms, many are not effective and there are no treatments that cure peripheral neuropathy.

PNRR is sponsored by the Foundation and controlled by Foundation along with the Foundation Scientific Advisory Committee composed of a group of scientists and clinicians collaborating to facilitate both basic and clinical research studies that will bring improved understandings of the causes and progression of peripheral neuropathy ("Scientific Advisory Committee"). A national and international adoption of this comprehensive patient registry will allow investigators to virtually pool their data and findings to facilitate research into the etiology of this disorder and identify evidenced-based diagnostic and treatment methodologies, preventative care and eventually a cure for peripheral neuropathy.

With this in mind, the Foundation recognizes the benefit of sharing data from the PNRR and the sharing of data generated by individual research projects back to the PNRR for further dissemination. As a result, the Foundation has developed this PNRR Data Use Policy to facilitate such data sharing.

Application Process

The PNRR Scientific Advisory Committee must approve all requests for access to samples and/or data ("PNRR Material") from the PNRR. The Scientific Advisory Committee will review application requests as outlined below and will approve or reject the application based on the nature of the request and the feasibility of providing the requested PNRR Material. The Scientific Advisory Committee is necessarily limited in approving requests for samples by the number of samples at the PNRR. Approvals from the

Scientific Advisory Committee must be obtained prior to allowing any access to the PNRR information for use as requested and approvals will be based upon considerations of scientific quality and validity as reflected in the application and will be granted only for research projects related to painful peripheral neuropathies. All approvals must be documented by the Scientific Advisory Committee. In the event the application for PNRR Material is rejected, FPN will communicate the reason for the rejection to the applicant.

The application form requests the following information:

- Organization Name
- Tax Status
- Study Title
- Principal Investigator Information, including Degree and Title
- Shipping Address
- Billing Address
- Research Study Information, including Persons Working on the Research Study, Specific Research Questions and Hypotheses to be Tested
- Description of Samples or Data Requested and Justification for Number of Samples Requested (if requesting samples)
- Details of Study Logistics
- Description of Anticipated Benefit of Research Study
- Status of IRB Approval
- Data Use Plan

Data Use and Material Transfer Agreements

As part of the application process, the applicant will receive with the Application the Data Use Agreement and Material Transfer Agreement. The applicant will complete the Application, execute the Data Use Agreement, and send both documents to the Foundation. The Data Use Agreement commits the applicant to use the PNRR Material only for the stated purposes and not to disclose the PNRR Material to third parties. Upon approval of any request by the Scientific Advisory Committee, FPN will notify the applicant of the approval. Upon approval of the application and executed Data Use Agreement, the Foundation will notify Indiana University, at which time the applicant, will enter into the Material Transfer Agreement with Indiana University to request release of PNRR Materials. Indiana University will confirm the approval of the request with FPN before releasing any PNRR materials.

Patient Policies

Patients will not be informed of the results of Research Projects involving information contained in the PNRR.

PNRR participants are free to withdraw from the PNRR at any time, and explicit directions about how to do that are outlined in the required PNRR informed consent form. If the participant withdraws, any PNRR Material related to that participant will be deleted from the PNRR and destroyed such that it will no longer be accessible. PNRR material related to the withdrawn participant that has already been released will not be recalled or destroyed.

Approved applicants that receive data or material must submit a brief progress report every six months and the Scientific Advisory Committee on a yearly basis will review access to the data and material.

De-identification of Data

Protecting the privacy of patient information is an important obligation of the PNRR. All PNRR Material has been de-identified to help ensure patient privacy is safeguarded as required by the Health Insurance Portability and Accountability Act and its applicable regulations.

Publication and Manuscript Policy

PNRR Material recipients must require its physicians, scientists, investigators, staff, and affiliates to acknowledge the Foundation in all published or unpublished articles, papers, and other scholarly publications written by any one or more of said persons that cite or reference the PNRR or make use of any PNRR data or material. Such acknowledgment should include the following statement: "The [insert name of research project] "Biospecimens and/or data used in the analyses presented in this article were obtained from the Peripheral Neuropathy Research Registry supported by the Foundation for Peripheral Neuropathy. As such, the investigators within PNRR contributed to the design and implementation of PNRR and/or provided data and collected biospecimens but did not participate in the analysis or writing of this report. PNRR consortium partners include (complete listing at FPN website, https://www.foundationforpn.org/peripheralneuropathyresearch/pnnr/consortium-partners/)."

The Foundation must receive an advance copy of all articles and manuscripts relating to the Research Projects making use of PNRR data or material. The Foundation will not review articles or manuscripts for scientific quality, but will review for compliance with these policies and/or the Data Use Agreement. If the article or manuscript does not comply with these policies and/or the Data Use Agreement, the Foundation may request edits to ensure compliance and such changes and edits will be made as reasonably requested by the Foundation.

Data Use Agreement

One of the items required as part of the application to receive PNRR Material, is a use plan to share the de-identified data derived from genotyping, mutation analysis, single nucleotide polymorphisms (SNPs) and other research and analysis developed using the PNRR Material back to Indiana University for purposes of maintenance as part of the PNRR databases. It is the Foundation's policy to encourage such sharing to occur in a timely manner. However, the Foundation understands the need for an organization to protect patentable and other proprietary data that may be generated as a result of the Research Project. As a result, such data, research and analysis should be shared back to the PNRR no later than immediately upon acceptance of the main findings from the final data set for publication or public disclosure of a submitted patent application, and/or as otherwise agreed upon with the Scientific Advisory Committee at the time the Research Project is approved.

SOP
Title: Researcher Request Review

Approved by: FPN Scientific Advisory Committee
Created Date: 2018 Revised:

1.0 Purpose: The purpose of this Standard Operating Procedure (SOP) is to establish the protocol under which requests for distribution of samples and data collected from the Peripheral Neuropathy Research Registry (PNRR) will be solicited, reviewed and processed.

2.0 Responsibilities: The review of researcher requests for samples from the PNRR will be received by the Foundation for Peripheral Neuropathy's Executive Director and reviewed by the Foundation's Scientific Advisory Board (SAB). The PNRR staff will ask the Indiana University PNRR Committee to review the request as well and provide comment on the suitability of the request.

3.0 Referenced Documents

- Application
- Data Use Policy
- Data Use Agreement
- Material Transfer Agreement for Transfer of Materials from Indiana University - PNRR
- Data Dictionary
- Sample & Data Pricing Policy

4.0 Protocols

4.1 Available Samples

Biological sample requests are all reviewed by the Foundation's SAB and then secondarily reviewed for availability by the IU-PNRR Committee.

4.2 Researcher request for PNRR data & samples

Researchers will be asked to submit to complete the "Application for Data & Samples, and Data Use Agreement." Application includes:

- An NIH biosketch or CV
- A description of the specific aims/research question/hypotheses
- Background/significance/rationale about why the specific aims are of interest and significance

- Methods which will include the type and number of samples being requested
- Preliminary analysis plan
- Information about clinical data that may be requested from the PNRR
- Following initial approval, researchers must also complete an MTA-From IU - PNRR

4.3 Review of submitted requests

The Foundation for Peripheral Neuropathy staff will initially review all submitted requests for completeness. The researcher will be contacted if any elements of the application are missing. Once all elements are submitted, the SAB will review for the application. The PNRR team can at any time initiate a conference call to discuss a particular request for samples. This conference call would include all available members of the PNRR.

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4.4 Review of PNRR Sample and Data Pricing Policy

After the application has been approved, the Foundation will use the price structure to calculate the researcher's cost. The Foundation will notify the research recipient of the charge by email for approval. Once approval has been received, the Foundation will issue the Invoice.

4.5 Material Transfer Agreement

To obtain samples from the PNRR, the researcher must complete an MTA-For transfer of the PNRR materials from Indiana University to the Provider which is signed by the appropriate representative from the researcher's institution as well as from Indiana University. After the application has been approved the PNRR SAC, Indiana University will contact the researcher to complete the MTA agreement

4.5 Distribution of samples and data

Once all steps have been completed, the researcher will be approved to receive samples and relevant PNRR variables. Details regarding the processing and shipping of requested samples will be provided by IU.

Researchers will also be sent the requested data variables when PNRR data is requested. The de-identified information will be distributed to the researcher in an excel file prepared by a PNRR coordinator.