



University of Pittsburgh

School of Medicine
Department of Neurology

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH REGISTRY

TITLE: UPMC Multiple Sclerosis and Related Disorders Research Registry

PRINCIPAL INVESTIGATOR: **Rock Heyman, MD**
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CO-INVESTIGATORS: **University of Pittsburgh Physicians Neurology Department Physicians and Research Staff of Multiple Sclerosis Center**
(Complete, current listing available upon request)

SOURCE OF SUPPORT: **Ethyl Vincent Charitable Trust**
University of Pittsburgh Neurology Departmental Funds

What is the purpose of this Research Registry?

Many advancements in medicine have resulted from research involving the collection and analysis of the medical record information of patients with a certain disease or condition. Because you are being seen by the University of Pittsburgh Physicians Department of Neurology for Multiple Sclerosis or a related disorder, we are asking for your permission to allow us to allow access to your medical information by the UPMC Multiple Sclerosis and Related Disorders Research Registry. By having access to the medical record information of many patients such as you through a research registry, researchers will be better able to conduct research studies directed at increasing our knowledge about Multiple Sclerosis and related disorders.

It is anticipated that the Research Registry will assist our investigators in two important ways.

First, it will allow researchers to review and study the medical records of many individuals to answer questions about your disease and its treatment.



Second, it will help researchers identify and recruit patients who are eligible for participation in future research studies. For example, physicians, nurses, and other researchers associated with the University of Pittsburgh Physicians Department of Neurology are also frequently involved in research studies directed at evaluating the safety and effectiveness of drugs, devices or procedures for the treatment of Multiple Sclerosis and related disorders. If you agree to participate in this Research Registry, your medical record information will be available to be reviewed by physicians and researchers to determine if you might qualify for various future research studies.

Who is being asked to participate in this Research Registry?

All adult patients who are seeking treatment or are being treated at the University of Pittsburgh Physicians Department of Neurology for Multiple Sclerosis or a related disorder are being asked to participate in this Research Registry.

What will my participation in this Research Registry involve?

If you agree to participate in the UPMC Multiple Sclerosis and Related Disorders Research Registry your medical record information will be placed into the Research Registry. This will permit research studies to be conducted on the medical record information contained within the registry. You are being asked to allow us to contact you if one of our researchers determines, through review of your medical record information, that you may be eligible for participation in a future research study at our center. Please note that if you qualify for any future research studies, you will be asked to sign a separate consent form that outlines in detail the nature of this research study, including its potential risks and benefits.

What are the possible risks of my participation in the Research Registry?

There are no risks of physical injury associated with your participation in the UPMC Multiple Sclerosis and Related Disorders Research Registry. Participation in this Research Registry does involve the possible risk that information about your health might become known to individuals outside of the University of Pittsburgh Physicians Department of Neurology.

We will attempt to preserve your medical record confidentiality by assigning a special research code number to you in the Research Registry. No personal identifiers (for example, your name, social security number, medical record number) will be stored in the Research Registry. Information linking the research code number to your name and other personal identifiers will be stored in a separate secure location. Access to any identifiable information about you that is contained within the Research Registry will be limited to investigators associated with the UPMC Department of Neurology and research staff.

What are the possible benefits of my participation in the Research Registry?

It is unlikely that you will receive any direct benefit as a result of your participation in the UPMC Multiple Sclerosis and Related Disorders Research Registry. Registry participation may allow you may be offered the



opportunity to participate in other research projects to help investigators better understand or treat Multiple Sclerosis or other related disorders however registry participation is not required to be considered for such studies.

Research performed with information from your medical record may be used for research studies directed at improving our knowledge and treatment of Multiple Sclerosis and related disorders and this knowledge may benefit patients with Multiple Sclerosis or related disorders in the future.

Will I or my insurance provider be charged for my participation in the Research Registry?

There will be no costs to you or your insurance provider to participate in this Research Registry.

Will I be paid for my participation in the Research Registry?

No, you will not receive any payment for participating in this Research Registry.

Who will know about my participation in this Research Registry?

Your neurologist and the neurology department staff will be able to identify your participation in this registry from an annotation in your medical record. You will not be identified by name in any publication of the results of research studies involving the use of your medical record information.

What is the nature of my medical record information that will be placed into the Research Registry?

All of your past, current and future medical record information related to your Multiple Sclerosis and related disorders will be recorded into the Research Registry. Since medical conditions and treatments not related directly to your Multiple Sclerosis and related disorders may affect Multiple Sclerosis and related disorders and/or its treatment, it is possible that all of your existing and future medical record information will be placed in the Research Registry.

This information will be collected from Multiple Sclerosis and related disorders Clinic records, hospital records and, if applicable, private physician records.

Who will have access to my identifiable medical record information contained in the Research Registry?

Access to your identifiable medical record information will be limited to investigators associated with the University of Pittsburgh Physicians Department of Neurology and research staff. A current, complete listing of these individuals will be provided to you upon your written request.

In addition, the following individuals may have access to your identifiable medical record information contained within this Research Registry:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review information contained within the Multiple Sclerosis and Related Disorders Research Registry to ensure that the Research Registry adequately protects your privacy.



In unusual cases, the researchers may be required to release your identifiable medical record information from the Research Registry in response to an order from a court of law.

For how long will my medical record information continue to be placed in the Research Registry and for how long will this information be used for research purposes?

We will continue your participation in the UPMC Multiple Sclerosis and Related Disorders Research Registry indefinitely, or until you withdraw your permission for participation in the Research Registry.

Your medical record may be accessed by the UPMC Multiple Sclerosis and Related Disorders Research Registry for research purposes for an indefinite period of time.

Is my participation in the Research Registry voluntary?

Your participation in the UPMC Multiple Sclerosis and Related Disorders Research Registry, to include the use of your medical record information for the research purposes described above, is completely voluntary. Whether or not you provide your permission for participation in this Research Registry will have no affect on your current or future medical care at the University of Pittsburgh Medical Center, affiliated health care provider, or your current or future relationship with a health care insurance provider. Whether or not you provide your permission for participation in this Research Registry will have no affect on your current or future relationship with the University of Pittsburgh.

May I withdraw, at a future date, my consent for participation in this Research Registry?

You may withdraw, at any time, your consent for participation in the UPMC Multiple Sclerosis and Related Disorders Research Registry, to include the additional collection of your medical record information and its further use for the research purposes described above. However, any research use of your medical record information prior to the date that you formally withdraw your permission will not be destroyed.

To formally withdraw your permission for participation in the UPMC Multiple Sclerosis and Related Disorders Research Registry you should provide a written and dated notice of this decision to the principal investigator of the Research Registry at the address listed on the first page of this consent form.

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of my participation in this Research Registry at any time, and that such future questions will be answered by the listed investigators or their research staffs. I understand that a copy of this consent form will be given to me.



I understand that any questions which I have about my rights as a participant in this Research Registry will be answered by the Human Subject Protections Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668).

By signing below, I agree to participate in the Multiple Sclerosis and Related Disorders Research Registry.

PARTICIPANT CONSENT

Participant's Signature

Date

Participant's PRINTED Name

Email Address (optional)

LEGAL AUTHORIZED REPRESENTATIVE CONSENT

Participant's Name (Print)

The above-named individual is unable to provide direct consent for study participation because

Therefore, by signing this form, I give my consent for his/her participation in this research study.

Legal Representative's Name (Print)

Legal Representative's Relationship to Participant

Legal Representative's Signature

Date

Page 5 of 6



University Of Pittsburgh
Institutional Review Board

Approval Date: 2/9/2015
Renewal Date: 3/9/2018

IRB #: PRO12010609

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this Research Registry to the above-named individual(s), and I have discussed the possible risks and potential benefits of participation in this Research Registry. Any questions the individual has about this Research Registry have been answered, and the listed investigators and their research staff will be available to address future questions as they arise.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

