PATIENT REGISTRY OR ORGANIZATION: The Transverse Myelitis Association Registry

STUDY NUMBER: 16-N-N021

PRINCIPAL INVESTIGATOR: Petra Kaufmann, M.D.
REGISTRY CONTACT: Gabrielle deFiebre, MPH

STUDY TITLE: **The NIH/NCATS GRDR® Program**
(Global Rare Diseases Patient Registry Data Repository)

Amendment C Approved by the IRB on 11/13/16
Continuing Review Approved by the IRB on 10/25/16
Registry and GRDR Repository consent

INTRODUCTION

We invite you to take part in a project with the The Transverse Myelitis Association Registry and sponsored by the National Institutes of Health (NIH).

We want you to know that:

Taking part in this research project is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at your organization, NIH, or with family, friends or your personal physician or other health professional.

For the purpose of this consent form, the "you" refers to the person diagnosed with a rare neuro-immune disorder, including acute disseminated encephalomyelitis (ADEM), neuromyelitis optica spectrum disorder (NMO/SD), optic neuritis (ON), or transverse myelitis (TM), including acute flaccid myelitis (AFM) about whom registry information will be collected. If you are signing this consent form on behalf of your child or another adult for whom you are the legal representative, "you" refers to your child or the person you are representing.

The person entering the information in the registry may be the patient or, for example, a family member or guardian who is legally responsible for the patient.

The term "study" in this consent form refers to the collection and sharing of information by and with research registries and repositories described in this consent form. It does not refer to specific research projects (often called "research studies") that may use the collected data.

Purpose

The purpose of this study is to enable The Transverse Myelitis Association Registry to collect and share information on people with acute disseminated encephalomyelitis (ADEM), neuromyelitis optica spectrum disorder (NMO/SD), optic neuritis (ON), or transverse myelitis (TM), including acute flaccid myelitis (AFM). The information obtained will be used for medical research.

Background

A patient "registry" or "repository" is a place that collects and stores patient medical information, family history and other related information for use in medical research. The Transverse Myelitis Association Registry collects information on individuals with acute disseminated encephalomyelitis (ADEM), neuromyelitis optica spectrum disorder (NMO/SD), optic neuritis (ON), or transverse myelitis (TM), including acute flaccid myelitis (AFM).

With this consent form, we ask your permission for The Transverse Myelitis Association Registry to collect your information and to send the information it collects from you to the NIH/NCATS GRDR® Program. The Transverse Myelitis Association Registry information may also be sent to other repositories or to researchers The Transverse Myelitis Association Registry selects.

Information in The Transverse Myelitis Association Registry, GRDR and other registries or repositories will be used for research to better understand acute disseminated encephalomyelitis (ADEM), neuromyelitis optica spectrum disorder (NMO/SD), optic neuritis (ON), or transverse myelitis (TM), including acute flaccid myelitis (AFM). It may also be used for other research that is not related to these rare neuro-immune disorders. It is hoped that the information will eventually be used for experimental clinical trials to try to develop new ways to diagnose or treat these diseases. Researchers need accurate information from as many affected people as possible to understand these rare neuro-immune disorders. In addition, researchers may access the GRDR repository to try to find people with specific conditions who may be eligible to participate in research studies. The Transverse Myelitis Association Registry may also be used to help The Transverse Myelitis Association better understand and serve the needs of our members. The Transverse Myelitis Association Registry is sponsored by The Transverse Myelitis Association. The GRDR repository is supported by the National Institutes of Health (NIH).

Who Can Participate

You may be eligible to participate if:

1. you have a rare disease
2. you are a member of The Transverse Myelitis Association
3. you
    a. are able to provide your consent, or
    b. are a child (younger than age 18) and have a parent or legal guardian who can provide consent, or
    c. are an adult who is not able to provide consent for yourselff and have a legally authorized representative who can provide consent for you

Who May Not Be able to participate

You may not be eligible to participate if you or your representative are unable to provide the information required for the repository for any reason

What will happen if you participate

If you participate, you will provide medical information on acute disseminated encephalomyelitis (ADEM), neuromyelitis optica spectrum disorder (NMO/SD), optic neuritis (ON), or transverse myelitis (TM), including acute flaccid myelitis (AFM). You will provide the information by filling out forms on paper or on a computer. You may be asked to obtain

some of the information from your medical records. If you are unable to enter the information yourself, you may have a parent, guardian, or someone you select help you enter it.

You will be asked to update the registry information at least once a year. The Transverse Myelitis Association Registry will send you a reminder each year. Please also contact The Transverse Myelitis Association Registry to update the registry information, if possible, whenever there is a change in your health or medication, or when new symptoms develop.

If you are enrolled as a minor, younger than age 18, you will be asked to provide your own consent, if possible, to continue to participate once you reach age 18.

Confidentiality

For sharing with the GRDR and other repositories, The Transverse Myelitis Association Registry will protect your privacy and confidentiality by removing identifying information, like your name, address and birthdate from the data that is shared. The "de-identified" data will be assigned a code. Only authorized people who work in The Transverse Myelitis Association Registry will have access to the key to the code. They are the only ones who will be able to identify you, if needed. Identifying information and the key to the code will not be shared with the GRDR, other repositories or researchers that receive data from The Transverse Myelitis Association Registry. The identified data in The Transverse Myelitis Association Registry and the de-identified data in the GRDR will be stored on secure computer servers.

Researchers from across the world will be able to request permission from The Transverse Myelitis Association Registry, the GRDR, or other repository to access your de-identified data. The data may be used for broad research purposes, including research unrelated to your disease or condition. Once the data is shared with the GRDR, you will not be able to limit its use to specific kinds of research. The policies of the GRDR and the other repositories will determine how the data may be used and who it will be shared with. The intent of the GRDR is to make data from those with rare disease as widely available as possible to qualified researchers.

Researchers may also use the GRDR repository data to find patients who may be eligible for their studies. If data in the GRDR repository shows that a contributing patient may be a good match for a research study, the researchers will provide a research proposal and contact letter to the GRDR, listing the code numbers of people they would like to contact. The GRDR will forward the information to The Transverse Myelitis Association Registry. If the registry agrees, they will forward the information to those patients in their registry who match the codes provided by the researcher. This contact will only be made by the TMA. Patients interested in the study can then contact the researcher directly for additional information and to join a study. Researchers will not be able to identify you from the information they receive and will not be able to contact you directly.

When results of research studies using registry or GRDR data are reported in medical journals or at scientific meetings, the people who take part are not named and identified. Your information in the GRDR registry may be viewed by NIH auditors or regulatory agencies in accordance with any applicable laws.

Risks, Inconveniences and Discomforts

There is minimal risk from taking part in this study. The information requested may include questions that can be sensitive and that you may feel uncomfortable answering. You do not have to answer any question that you do not want to answer.

Although we will protect your privacy and confidentiality to the extent possible, there is a small chance that those with a rare disease might be identifiable from the information in the registry. Your privacy and confidentiality might also be

at risk if there were a breach in The Transverse Myelitis Association Registry computer system. You will be notified if any such breach occurs.

Anticipated Benefit

Participation in this study will not benefit you directly---personally, medically or financially. However, your participation may help increase understanding of your disease or condition or other diseases. Including information from many people with rare diseases may help speed up research. It is hoped that such research will eventually improve the diagnosis and treatment of these disorders.

Right of Withdrawal and Conditions for Early Withdrawal

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. The Transverse Myelitis Association Registry can remove you from the study at any time if you are unable to comply with the requirements. For example, The Transverse Myelitis Association Registry may remove you and your data if you knowingly provide false or misleading information or if you attempt to gain access to others' information. If you withdraw, any data that can be identified as yours will no longer be released to the GRDR or other repositorie*s.* Information that has already been integrated in the GRDR repository will remain in the GRDR and will continue to be shared with researchers. It will not be removed.

Results From use of GRDR information

Results obtained through use of your information in the GRDR will not be returned to you. The Transverse Myelitis Association Registry may keep published research papers which used The Transverse Myelitis Association Registry data that they can share with you.

Termination

Your The Transverse Myelitis Association Registry information will be kept in the GRDR indefinitely. If The Transverse Myelitis Association Registry ceases operation, the information it contains will be transferred to other registries or repositories or destroyed. If the GRDR program is closed, NIH plans to return the data in the GRDR repository to the submitting registry.

Alternatives to Participation or Treatment

This study does not provide treatment. You may choose not to participate.

Compensation and Travel costs

There is no cost for participating in this study.

You will not be compensated for participation in this study. You may be charged by your own health care providers if you need to obtain medical records from them in order to complete the requested information.

It is possible that researchers may develop a commercial product based in part on information they obtain from the GRDR or other registries or repositories, including your information. You will not be compensated for any commercial developments that may derive from use of information provided to The Transverse Myelitis Association Registry, the GRDR, other repositories or to researchers.

ADDITIONAL INFORMATION

1. Policy Regarding Research-Related Injuries. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

2. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact The Transverse Myelitis Association Registry at 855-380-3330 ext 6.

You may also contact the Principal Investigator of this study, Dr. Petra Kaufmann about the GRDR study at: kaufmanp2@mail.nih.gov

3. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/Legal Representative _____ Date _____

Print Name _____

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.

Signature of Parent(s)/Guardian _____ Date _____

Print Name _____

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian _____ Date _____ Print Name _____

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM OCTOBER 25, 2016 THROUGH OCTOBER 24, 2017.

Signature of Person obtaining consent _____ Date _____

Print Name _____

Signature of Witness _____ Date _____

Print Name _____