The SRNA Registry

Informed Consent Form

Introduction

The mission of The Siegel Rare Neuroimmune Association (SRNA) is to support and advocate for individuals and their families diagnosed with rare neuroimmune disorders of the central nervous system. SRNA promotes awareness and empowers patients, families, clinicians, and scientists through education programs and publications. We aim to advance the scientific understanding of and therapy development for these rare neuroimmune disorders by supporting the training of clinician-scientists dedicated to these rare disorders and by supporting basic and clinical research. The disorders covered by SRNA's work include Acute Disseminated Encephalomyelitis (ADEM), Acute Flaccid Myelitis (AFM), MOG Antibody-Associated Disease (MOG-Ab disease), Neuromyelitis Optica Spectrum Disorder (NMOSD), Optic Neuritis (ON), and Transverse Myelitis (TM).

Purpose of the research

A registry is a place to collect and store detailed information about individuals with a specific disease or disorder. In this case, The SRNA Registry is for individuals with rare neuroimmune disorders (acute disseminated encephalomyelitis, acute flaccid myelitis, neuromyelitis optica spectrum disorder, MOG antibody-associated disease, optic neuritis, or transverse myelitis).

Information in The SRNA Registry will be used for research to better understand these disorders. It may also be used for other research that is not related to these rare neuroimmune 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 neuroimmune disorders. In addition, researchers may access The SRNA Registry to try to find people with specific conditions who may be eligible to participate in research studies. The SRNA Registry may also be used to help The Siegel Rare Neuroimmune Association better understand and serve the needs of our members.

By collecting this information, researchers can understand the course of the disease, including:

- Study what symptoms individuals have
- Study what treatments individuals receive and whether improvement was seen after the treatment
- Study how to help medical professionals improve how they treat individuals with rare neuroimmune disorders

Participant Selection

We are inviting you to participate in this study because you are an individual with a rare neuroimmune disorder (acute disseminated encephalomyelitis, acute flaccid myelitis, neuromyelitis optica spectrum disorder, MOG antibody-associated disease, optic neuritis, and transverse myelitis), or the parent or legal guardian of a child with one of these disorders.

Consent to participate must be provided by an eligible adult participant or a legal guardian if the participant is under the age of 18 or is an adult who is unable to provide consent for him/herself.

Parents or a legally authorized representative can also enroll on behalf of patients who are deceased. When a legal guardian/representative is completing The SRNA Registry, an additional signature is required for participant assent, which is required if an individual is 7 years of age or older and is cognitively able to provide assent.

Voluntary Participation

Your participation in this research study is entirely voluntary. It is your choice whether to participate or not. You may change your mind later and stop participating even if you earlier agreed to participate. The SRNA Registry can remove you from the study at any time if you are unable to comply with the requirements. For example, The SRNA 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 researchers requesting de-identified data. Information that has already been shared with researchers or used in reports of registry results cannot be removed.

Procedures

If you agree to be a part of this study, you will participate in a survey that should not take more than 60 minutes to complete.

You also will be asked to update your profile and information semi-annually or annually. We will send out notifications to remind you.

Your responses are entirely confidential. All identifying information will be removed and will not be included in analysis of the data.

Risks and Benefits

The risks to participating in this study are minimal. There is no direct medical benefit to an individual from being in The SRNA Registry.

Reimbursements

You will not be provided with any payment or reimbursement to take part in the research.

Confidentiality

The information you provide will not be shared with anyone outside the research team without your permission. All identifying information will be removed and you will not be identified in any way in reports of this data.

For sharing with researchers, The SRNA Registry will protect your privacy and confidentiality by removing identifying information, like your name, address and birthdate from the data that are shared. The "de-identified" data will be assigned a code. Only authorized people who work at SRNA 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 other repositories or researchers that receive

ta in The SRNA Registry will be stored in

Researchers from across the world will be able to request permission from The SRNA Registry 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 are shared with researchers, you will not be able to limit its use to specific kinds of research.

Researchers may also use The SRNA Registry data to find patients who may be eligible for their studies. If data in The SRNA Registry 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 SRNA, listing the code numbers of people they would like to contact. SRNA will forward the information to those patients who match the codes provided by the researcher. This contact will only be made by SRNA. 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 data are reported in medical journals or at scientific meetings, the people who take part are not named and identified. Your information in The SRNA Registry may be viewed by NIH auditors or regulatory agencies in accordance with any applicable laws.

Your information in The SRNA Registry will be kept in the registry indefinitely.

Optional Data Sharing with University of Texas Southwestern Medical Center (UTSW)
Dr. Benjamin Greenberg at UTSW is partnering with SRNA to share data about registry participants with TM who want their information shared. Dr. Greenberg is the Director of UTSW's Transverse Myelitis and Neuromyelitis Optica Program. Dr. Greenberg's study, entitled Comprehensive Outcomes Registry Exploring Transverse Myelitis Study (CORE TM Study), will create a registry focused on short and long-term outcomes, and further inform the development of an outcomes measure for use in clinical trials. The CORE TM Study will collect similar information as The SRNA Registry, but will also include review of medical records. The CORE TM study is only enrolling individuals with TM. **If you would like SRNA to share your information and responses with UTSW, please check yes below**. Dr. Greenberg's team will contact you and may ask for additional information and medical records. **If you do not want your information shared, please check no below.**

I give permission for SRNA to share my data with Dr. Greenberg's team at UTSW
_____YES
_____NO

Who to Contact
If you have any questions or want any additional information about this study you may contact:

Gabrielle deFiebre, MPH
The Siegel Rare Neuroimmune Association
1787 Sutter Parkway
Powell, OH 43065-8806

This research project (IRB# 2302) has been reviewed and approved by the Institutional Review Board of the Institute for Family Health on July 31, 2018. If you wish to find out more about the IRB, contact Saskia Shuman at 212-633-0800.

Certificate of Consent

I have read the foregoing information. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.

Name of Participant: _____

Signature of Participant: _____

Date: _____
Day/month/year

THE INSTITUTE FOR FAMILY HEALTH

Institutional Review Board (IRB)
Approval Date: 08/22/2019
Expiration Date: 08/21/2020
Administrative Approval: SS