Providence Brain and Spine Institute
9135 S.W. Barnes Road, Suite 363
Portland, OR 97225
t: 503.216.1055
f: 503.216.1021
www.providence.org/brain

Oregon Neurosciences Program

PROVIDENCE Brain and Spine Institute

ADDENDUM INFORMED CONSENT FORM

Title: Switching relapsing multiple sclerosis patients treated with natalizumab (Tysabri ®) at risk for progressive multifocal leukoencephalopathy to teriflunomide (Aubagio®): Is this safe and effective?

Analysis of John Cunningham virus (JCV) antibody index in MS patients treated with teriflunomide (SWITCH-JCV) (PH&S IRB # 14-011B)

Principal Investigator: Stanley Cohan, MD, PhD

Sponsor: Providence Health & Services

Funder: Sanofi Genzyme

Protocol: SWITCH Protocol Addendum, dated 04 Dec 2018

INTRODUCTION

The purpose of this addendum consent form is to update you about new research questions that came up during the course of the main study. Make sure you understand what is written, and ask as many questions as needed before you sign this addendum consent form.

All other information in the original consent form you signed is still valid.

Please read the information carefully and feel free to ask questions. It may be helpful for you to discuss this information with your family and friends. If you choose not to take part, you will not lose the regular care you receive from your doctors.

Please indicate whether or not you would like to participate in this additional blood draw on the signature page of this form. You will be given a copy of your signed consent form.

SUB-STUDY BACKGROUND

A drug called leflunomide, which is very similar to teriflunomide, has been found to reduce or eliminate BK virus in patients who received kidney transplants. BK virus and JC virus both belong to the polyoma virus family and are closely related.

Researchers think it is possible that teriflunomide may reduce or eliminate the amount of JC virus in your body, and thereby reduce the risk of developing progressive multifocal leukoencephalopathy (PML).

Providence Health and Services (Oregon)
IRB Number: PDX14-011
IRB Approval Date: 10/29/2019
IRB Parent Number: PDX14-011

PROCEDURES
For all patients who enrolled in the SWITCH trial and received teriflunomide, the study team would like to collect a blood sample to see if there is an impact on your JC virus status. This will be done at a Quest Diagnostic Lab near you. Your study team will discuss the procedure with you.

The sample requires 3-5 milliliters (1 teaspoon) of blood to be sent for anti-JCV antibody Index test. This blood tests detects antibodies to JC Virus, which indicates exposure to the virus. The results will be scanned into your electronic medical record, however your MS treatment will not change based on the results of this blood test.

GENERAL INFORMATION
Taking part in this sub-study is voluntary. Refusing to take part will not affect the health care benefits you have. If you decide to take part, you are free to stop at any time without any effect on your medical care or your relationship with your doctor(s) or Providence Health & Services.

COSTS
You and your health insurance company will be paying for the costs of your routine medical care, including any costs of treating your MS while in this sub-study, and medicines to manage any side effects.

You or your insurance company will not have to pay for the JC virus test described in this consent, or the phone visit with the study coordinator. Providence is responsible for making sure these charges are billed to this sub-study and not you or your insurance company.

LIABILITY
If you are injured as a result of taking part in this sub-study, all of the necessary medical facilities are available for treatment, as is reasonably possible. You or your insurance will be billed for treatment, even for injuries that are a direct result of taking part in the study.

You do not give up any of your legal rights by signing this consent form and taking part in this study.

QUESTIONS
You are free to ask questions about this study at any time. Any questions you have about this research study or a research-related injury can be answered by:

Study Doctor: _____ at _____

Study Coordinator: _____ at _____

Any questions you have about your rights as a research subject will be answered by the Providence Health & Services Institutional Review Board at (503) 215-6512.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Providence Health and Services (Oregon)
IRB Number: PDX14-011
IRB Approval Date: 10/29/2019
IRB Parent Number: PDX14-011

CONSENT: I have read this Addendum consent form, and my questions have been answered to my satisfaction. Please initial **one** option below:

_____ I agree to provide an additional blood sample

OR

_____ I do not agree to provide an additional blood sample

_____
Name of Patient (Please Print)

_____
Signature of Patient Date

_____
Name of Person Obtaining Consent (Please Print)

_____
Signature of Person Obtaining Consent Date

Providence Health and Services (Oregon)
IRB Number: PDX14-011
IRB Approval Date: 10/29/2019
IRB Parent Number: PDX14-011