CAROLINAS HEALTHCARE SYSTEM

SUBJECT INFORMATION AND CONSENT FORM

Name of Research Study: JCV Antibody Program in Patients with Relapsing Multiple Sclerosis Receiving or Considering Treatment with Tysabri®: STRATIFY-2

Protocol #: 101JC402

Sponsor: Biogen Idec

Principal Investigator Name: **Michael D. Kaufman MD**

Research Site Address(es): Neuroscience and Spine Institute
Carolinas Medical Center
1010 Edgehill Road North
Charlotte NC 28207

Daytime telephone number(s): 704-446-1349

24-hour contact number(s): 704-355-4088

PURPOSE OF THE SUBJECT INFORMATION AND CONSENT FORM

This Subject Information and Consent Form may contain words you do not understand. Please ask Dr. Kaufman or the study staff to explain any words or procedures that you do not clearly understand.

The purpose of this form is to give you information about the research study and, if signed, will give your permission to take part in the study. The form describes the purpose, procedures, benefits, risks, discomforts and precautions of the research study. You should take part in the study only if you want to do so. You may refuse to take part or withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. Please read this Subject Information and Consent Form and ask as many questions as needed. You should not sign this form if you have any questions that have not been answered to your satisfaction.

INTRODUCTION

Dr. Kaufman is asking you to participate in this research study sponsored by Biogen Idec, Inc at the Multiple Sclerosis (MS) Center/Carolinas HealthCare System (CHS) and Neuroscience and Spine Institute. You are being asked to take part because you have been previously diagnosed with multiple sclerosis and have been, or are considering, taking Tysabri®.

Biogen Idec, the maker of Tysabri®, has established the JC virus (JCV) Antibody Program in the United States: STRATIFY-2. Tysabri® is associated with an increased risk of Progressive Multifocal Leukoencephalopathy (PML) and JC is the virus that is linked to PML. Biogen Idec has developed a blood test that measures antibodies to JCV. Antibodies are produced by the body's immune system when it detects foreign substances. It is thought that approximately half of MS patients have antibodies to JCV.

The purpose of this study (STRATIFY-2) is to better understand whether antibodies to JCV may be used to predict whether a patient is at higher or lower risk for developing PML. This is a research question and it is not known whether detection of antibodies to JCV in an individual can predict their risk of developing PML. For this reason, the test result from this study should not be used in treatment decisions. You and Dr. Kaufman will be given the results of your antibody detection tests.

You will be one of approximately 8,000 people with MS in the United States involved in this research study, and your participation will last for approximately 2 years. There is no drug treatment provided in this study.

HOW THE STUDY WORKS

If you agree to take part in this study, you will first sign this Subject Information and Consent Form before any study-related procedures are performed.

If you choose to participate in this study, a sample of your blood (10 ml, or approximately 2 teaspoons) will be taken up to 3 times: once at the start and then yearly for up to 2 years. Blood samples will be collected at your regularly scheduled clinic visits. You will continue to receive your routine MS care with your doctor.

RISKS

Risks of Blood Drawing:

Risks associated with blood drawing may include pain, bruising and infection. Rarely, a person faints. You will have about 10 ml (2 teaspoons) of blood drawn at each yearly visit. The blood sample is usually taken at the same time as routine blood tests are being done. Therefore, there is usually no extra needle prick, but the blood draw may take a few seconds longer.

NEW FINDINGS

During the course of the study, you will be informed of any important new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research study or new alternatives to participation in this study that might change your decision to be in the study. You may contact Dr. Kaufman at any time after your participation ends to find out if any new information about this study has become available.

BENEFITS

There are no direct health benefits to you for participating in this study. However, the information collected in this study may help Biogen Idec and Dr. Kaufman better understand JCV and risk factors for developing PML. You will be informed in a timely manner if information becomes available that may affect your willingness to participate in this study.

PAYMENT FOR PARTICIPATION

You will not be paid for your participation in this study.

ADDITIONAL COST

Study related blood draws will be free of charge. Only the cost of the antibody test will be paid for by Biogen Idec. Expenses related to your therapies, such as doctor charges, other office visits or other tests are not covered under this study. You or your medical insurance provider will be responsible for all costs associated with your medical treatment unrelated to this study.

Your insurance company may not pay for research treatments. You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

COMPENSATION FOR RESEARCH-RELATED INJURY

If you have an injury that is related to a protocol-required procedure, Biogen Idec will pay for the reasonable cost of necessary medical care to the extent the cost is not paid by your medical insurance or another party. A protocol-required procedure is a procedure that is not standard of care and which would not have been performed except for your participation in the study. Your study doctor will decide what medical care you will need. Biogen Idec will not provide any other kind of compensation, such as lost wages, disability, or discomfort.

LEGAL RIGHTS

The above section does not restrict your right to seek legal assistance. You do not waive any legal rights by signing this Subject Information and Consent Form.

VOLUNTARY PARTICIPATION

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not be in the study, that will not in any way harm your relations with your doctors or with Carolinas HealthCare System. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Carolinas HealthCare System.

WITHDRAWAL

Your doctor, Biogen Idec, or the FDA has the right to stop your participation in the study at any time, with or without your consent, for any of the following reasons: If you need a treatment not allowed in this study, if you do not keep appointments, if you become pregnant, or if the study is canceled by the FDA or the sponsor company. If you decide to stop participating, your medical

care will not be affected and you will not be penalized or lose any benefits to which you would otherwise be entitled to for the treatment of your MS. If you decide to leave this study before it ends, Biogen Idec will still use the data collected before your withdrawal.

ALTERNATIVE TO PARTICIPATION

Your alternative is not to participate.

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify you. All information collected in this study will not identify you by name but rather by a patient number or your initials and date of birth. Your record for this study may, however, be reviewed and/or photocopied by the drug/device manufacturer, by Carolinas HealthCare System, by Copernicus Group Independent Review Board (IRB), or by representatives of the Food and Drug Administration or other government agencies. To that extent, absolute confidentiality cannot be guaranteed.

STUDY SAMPLES:

Your blood samples related to the study will be sent to a laboratory for testing for antibodies to JCV, and the test results will be given to Dr. Kaufman or his associate. It is unknown whether antibodies to JCV predict your risk of developing PML.

Biogen Idec and its designees will also have access to your test results. Your blood will be kept in long-term storage for future JCV research or until destroyed by Biogen Idec. Future testing related to JCV research may be conducted on your samples. No genetic testing will be performed.

FINANCIAL INTEREST OF INVESTIGATOR

The study doctor is paid as a consultant to Biogen Idec, and/or receives speaking or other fees from Biogen Idec. You may ask the study doctor any questions necessary to assure yourself that these benefits have not overly influenced the doctor's request for you to take part in this study. If you have concerns about this payment, ask the study doctor for more information. The decision whether to enroll in the study is yours alone. You should have all the information you need to be comfortable with your decision.

QUESTIONS

If you have any questions about your participation in this research study or if you feel that you have experienced a research-related injury, contact:

Principal Investigator: **Michael D. Kaufman MD**

Daytime telephone number(s): 704-446-1349

24-hour contact number(s): 704-355-4088

If you have questions about your rights as a research subject, you may contact the Copernicus Group IRB at 1-888-303-2224 (toll free). An Independent Review Board is a group of scientific and non-scientific individuals who perform the initial and ongoing ethical review of the research study with the study subject's rights and welfare in mind. Copernicus Group IRB has reviewed and approved the research study described in this Subject Information and Consent Form. If you have study-related comments, complaints or concerns, you should first contact the study investigator, Dr. Kaufman. Please call the IRB if you want to talk to someone other than the study investigator or have difficulty reaching the study investigator. For further information regarding the clinical trials process and your role as a research subject, you may visit the Copernicus Group IRB website at www.cgirb.com.

HIPAA AUTHORIZATION

If you wish to take part in this research study, you will be asked to sign this consent and authorization form. It allows the study sponsor and the study investigator to collect, process and pass on to Biogen Idec any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the clinical study investigator, Dr. Kaufman, and research staff
- the study sponsor and/or its associated companies
- regulatory or other governmental authorities of the United States and other countries
- other persons authorized by the study sponsor
- Carolinas HealthCare System employees
- Copernicus Group IRB
- other persons or agencies as required by law or allowed by federal regulations

You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study
- compare and pool blood test results with those of other subjects in clinical studies

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Carolinas HealthCare System.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed, it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

You have been told that if you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study investigator and sponsor will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. If you wish to revoke authorization to use your personal information, you will notify the study doctor, Dr. Kaufman, in writing:

Michael D. Kaufman MD
CMC – Neuroscience & Spine Institute
Department of Neurology
MS Center
1010 Edgehill Road North, Charlotte, NC 28207
Telephone: 704-446-1349

Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

SUBJECT'S STATEMENT OF CONSENT

JCV Antibody Program in Patients with Relapsing Multiple Sclerosis Receiving or Considering Treatment with Tysabri®: STRATIFY-2

- This is a research study collecting blood samples.
- I have been given sufficient opportunity to consider whether to participate in this study.
- My taking part in this research study is voluntary. I may decide not to take part or to withdraw from the research study at any time without penalty or loss of benefits or treatment to which I am entitled.
- If I meet the criteria, I would like to take part in this research study, and my doctor may enroll me in the research study.
- The research study may be stopped at any time without my consent either by the study doctor or by the company sponsoring the research.
- My study doctor will be receiving payment from the sponsor to conduct the research.
- I have had an opportunity to ask my study doctor questions about this research study. My questions so far have been answered to my satisfaction.
- I have been told how long I may be in the research study.
- I have been informed of the procedures and tests that may be performed during the research study.
- I have been told what the possible risks and benefits are from taking part in this research study.
- I authorize the use of my personal health information.
- I do not give up my legal rights by signing this form.
- I have been told that prior to any study related procedures being performed, I will be asked to voluntarily sign this Subject Information and Consent Form.
- I will receive a signed and dated copy of this Subject Information and Consent Form.
- I have been told that all specimens and samples obtained from me during my participation in this study will be used and kept for the purposes described in this Subject Information and Consent Form, and all data and materials created during this study will be the property of Biogen Idec. I further have been told that Biogen Idec has no plans to pay me or to share any potential profits that Biogen Idec may receive from such specimens, samples, data, or materials.

_____	_____	_____
Subject Print Name	**Date**	**Time**
_____	_____	_____
Subject Signature	**Date**	**Time**

I certify that the information provided was given in language that was understandable to the subject.

Print Name of Person Obtaining Consent	**Date**	**Time**
Signature of Person Obtaining Consent	**Date**	**Time**
Investigator Print Name	**Date**	**Time**
Investigator Signature	**Date**	**Time**