Official Title:	NAtalizumab for Prevention of Post-partum Relapses in patients with Multiple Sclerosis (NAPPREMS)
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Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
1010 Main Street, 2nd Floor, Buffalo, NY 14203

Adult Consent to Participate in a Research Study

Title of research study: ***Natalizumab for Prevention of Post-Partum Relapses in Patients with Multiple Sclerosis***

Version Date: ***05/19/2019***

Investigator: ***Bianca Weinstock-Guttman, MD***

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because you are a female patient with multiple sclerosis who has had a baby within the last 30 days.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to evaluate if natalizumab (Tysabri), given monthly, is effective in preventing postpartum relapses. After giving birth women may experience an increase in MS relapses. Women have many options for managing their MS after giving birth. Treatment with natalizumab is only one of them. This study will observe and compare a group of postpartum women who have chosen to be treated with natalizumab to those women who have selected other treatment options.

How long will the research last and what will I need to do?

We expect that you will be in this research study for approximately 1 year.

You will be asked to attend your regularly scheduled clinical visits, which typically occur every 3 months, and, if you are being treated with Tysabri, come to clinic for your infusions as they are scheduled clinically. You will be asked complete questionnaires every 6 months.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

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Is there any way being in this study could be bad for me?

There are no physical risks associated with the evaluations (the physical exam, neurological exam, and collection of vital signs) that are performed as part of this study. It is possible you may experience fatigue from completing the questionnaires.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

There are no benefits to you for participating in this study. However, the information collected in this study may help women with a similar condition in the future.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study.

Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-829-5037. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 25 women here will be in this research study out of 30 women in the entire study nationally.

What happens if I say yes, I want to be in this research?

You will not be given an MS therapy as part of your participation in this study.

The MS therapy you are given will be determined by you and your doctor. You and your doctor will decide what is best for you.

Your participation in the study involves the following tests and assessment at each of the visits:

Visit 1/Screening/Enrollment:

- Review of eligibility criteria
- Review of your medical history

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- Collection of demographic information, including information about your MS and MS treatment history
- Physical exam
- Neurological exam
- Vital signs
- Completion of 3 questionnaires
- If your doctor has ordered an MRI the results will be collected from your medical record.
- If you have decided to start an MS therapy that requires that your blood be taken and evaluated at a clinical laboratory prior to beginning the treatment, the results will be collected from your medical record.
- If you have decided to start an MS therapy, you will begin treatment at this visit, or shortly after this visit.

Visit 2/Week 12:

- Neurological exam
- Vital signs
- Review of MS symptoms and relapses since your last visit
- If you are taking an MS therapy that requires that your blood be taken and evaluated at a clinical laboratory while on the treatment, the results will be collected from your medical record.

Visit 3/Week 24:

- Neurological exam
- Vital signs
- Review of MS symptoms and relapses since your last visit
- Completion of 3 questionnaires
- If you are taking an MS therapy that requires that your blood be taken and evaluated at a clinical laboratory while on the treatment, the results will be collected from your medical record.

Visit 4/Week 36:

- Neurological exam
- Vital signs
- Review of MS symptoms and relapses since your last visit
- If you are taking an MS therapy that requires that your blood be taken and evaluated at a clinical laboratory while on the treatment, the results will be collected from your medical record.

Visit 5/Week 48:

- Neurological exam
- Vital signs
- Review of MS symptoms and relapses since your last visit
- Completion of 3 questionnaires
- If your doctor has ordered an MRI the results will be collected from your medical record.
- If you are taking an MS therapy that requires that your blood be taken and evaluated at a clinical laboratory while on the treatment, the results will be collected from your medical record.

If you decide to be treated with natalizumab (Tysabri), you will receive monthly infusions. You will also have clinical blood work collected every 12 weeks which is a requirement of being treated with natalizumab. The results of this clinical blood work will be collected from your medical record for the study.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

There are no physical risks associated with the evaluations (the physical exam, neurological exam, and collection of vital signs) that are performed as part of this study. It is possible you may experience fatigue from completing the questionnaires.

Some information may be collected from your medical record, as a result of this, there is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

You may receive treatment with an MS therapy during your participation in this study. Every therapy has its own risk associated with it. The risk related to this medication will be discussed with you by your doctor.

This study is not providing free medical services to you. Your medication, regardless of what medication you are taking, will not be provided by the study, you will continue to receive it as you would if you were not participating in the study.

The clinical laboratory tests that may be required because of the medications you are taking are due to standard of care treatment and are billable to you or your insurance through normal billing practices. Standard of care means necessary for the care of a medical issue as determined by your doctor and not necessary for this study.

There may be clinic or doctor visits and procedures, including MRIs, you will have during your participation in the study that are due to standard of care treatment and are billable to you or your insurance through normal billing practices. Standard of care means necessary for the care of a medical issue as determined by your doctor and not necessary for this study.

Your insurance may not cover some or all of the standard care services. You may want to talk to your insurance company and review your specific benefits and coverage before deciding to participate. You will be responsible for normal co-pays, deductibles and non-covered services that are not the responsibility of the study. Some procedures require Pre-Certification (or prior authorization) from your insurance company. Pre-Certification (or prior authorization) is not a guarantee of payment.

You can still be in the study even if your insurance denies coverage for your standard of care treatment or if you are uninsured. If your insurance denies coverage you will be charged for all bills that are not the responsibility of the study. The study staff will be able to provide more information to you.

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What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

A subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

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

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

What else do I need to know?

Who is paying for this research?

This research is being funded by Biogen Idec.

Dr. Hojnacki and Dr. Weinstock-Guttman have been paid travel support and consultancy fees by the sponsor of this research.

Will I get paid for my participation in this research?

You will not be paid for participating in this study.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What individually identifiable health information will be collected about you as part of this research study?

- ✓ Information from your full medical records.
- ✓ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to create or provide this information for research use?

- ✓ KALEIDA Health, Buffalo NY
- ✓ Principal Investigator or designee
- ✓ UBMD Neurology

C. Who is authorized to receive the information from the information providers identified in (B)?

- ✓ Principal Investigator or designee

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D. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

- ✓ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment
- ✓ The sponsor of this research study Biogen MA
- ✓ The organization(s) responsible for administering this research: Research Foundation of SUNY and UBMD Neurology

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

E. How long are the information providers listed in (B) authorized to provide your information for this research project?

This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information. The researchers may continue to rely on this authorization to acquire protected health information about you unless you revoke this authorization in writing.

F. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the

investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Bianca Weinstock-Guttman, MD
UBMD Neurology
1010 Main Street, 2nd Floor
Buffalo, NY 14202

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

G. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	