

Permission to Take Part in a Human Research Study

Title of Research Study: *Ocrevus Zunovo for Patients with Multiple Sclerosis: Mixed Methods on Barriers and Facilitators to Use and Retention*

Principal Investigator: Farrah Mateen, MD, PhD

Supported By: This research is supported by Genentech, Inc

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: Genentech, Inc

The study sponsor does not have any role in the conduct of the study or the decision to publish the results. The project was independently designed by the investigator.

If your doctor is also the person responsible for this research study, please note that your doctor is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:

The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are diagnosed with multiple sclerosis (MS), and are either planning to start have recently started treatment with Ocrevus Zunovo (OZ).

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?

This research is being done to understand the effects of Ocrevus Zunovo (OZ), a specific type of Ocrelizumab treatment, on people living with MS. Ocrelizumab is an FDA-approved disease modifying treatment that's increasingly the treatment of choice for individuals with MS in the USA and globally. OZ is an FDA-approved twice yearly injection for patients with relapsing and primary progressive MS. This study seeks to follow patient-reported outcomes and satisfaction while they are taking OZ.

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

We expect that you will be in this research study for 12 months.

You will be asked to complete 3 visits, including a baseline visit and follow-up visits after 6 months and 12 months. At these visits, you will complete surveys to report medication dosing, adherence, tolerability, and satisfaction. In addition, the surveys will include self reported measures of quality of life.

You can find more detailed information about the study procedures in the **What happens if I say, "Yes, I want to be in this research"?** section.

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

You may experience emotional distress or be psychologically burdened by repeated testing and surveying throughout the study.

You may be subject to an unforeseen data breach during the conduct of the study through data hacking or other means due to human error or technological problems.

You can find more detailed information about the risks of this study in the **"Is there any way being in this study could be bad for me? (Detailed Risks)"** section.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits for future individuals living with MS include establishing the safety of Ocrevus Zunovo and evaluating progression independent of relapse activity. More data from patients taking this medication can help patients and providers make better, more informed decisions about treatment plans.

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

Participation in research is completely voluntary. You decide whether or not to participate. If you choose not to participate, there will be no penalty to you or loss of benefit to which you are entitled.

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

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team. Ask questions as often as you want. Farrah Mateen, MD, PhD is the person in charge of this research study. You can call her at 410-935-5181 (available M-F 9 am to 5 pm) or email her at farrah.mateen@northwestern.edu with questions about this research study.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-1376 or irbcompliance@northwestern.edu if:

- The research team is not answering your questions, concerns, or complaints.

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- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 75 people will be in this portion of the research study, receiving Ocrevus Zunovo.

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

If you choose to take part in this research study, you will be asked to sign and date this consent form before any study-related activities described below are performed. You will have the opportunity to ask the research team any questions if you need clarification.

Once enrolled into the study, both you will be asked to fill out various questionnaires. These questionnaires will include reports on medication dosing, adherence to medicine, tolerability, and satisfaction. In addition, you will also be asked to self assess yourself on a scale that measures quality of life. You will complete these questionnaires at the time of enrollment, and a follow-up study visits after 6 months and 12 months.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

1. Completing surveys, participating in self-assessments, and providing various measures at the enrollment visit and 2 follow-up visits.
2. You will be required to keep in touch with the study team if there are any changes to your medication treatment regimen.

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 decide to leave the research, contact the investigator so that the investigator can take the appropriate steps.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment. If you withdraw from the study, any data collected until the time of your withdrawal will be retained for study related purposes. However, no additional data will be collected after this moment. You may request someone from the study team to remove your data.

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

You may experience emotional distress or be psychologically burdened by repeated testing and surveying throughout the study.

You may be subject to an unforeseen data breach during the conduct of the study through data hacking or other means due to human error or technological problems. This may lead to inadvertent disclosure of the MS diagnosis to others. All available measures will be taken to avoid such incidents and warn participants of these risks during the consent process. This study involves the use of your identifiable, personal information, and there is a chance that a loss of

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confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?"**

We will do our best to protect your data and samples during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that people who are not supposed to might access your data and samples. In either case, we cannot reduce the risk to zero.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, the information gathered from the study can have possible benefits for future individuals living with MS, particularly those taking Ocrevus Zunovo. The results of the questionnaires and clinical data will help provide satisfaction of treatment of patients taking Ocrevus Zunovo will be established through questionnaires. More data from patients taking medications can help patients and providers make better, more informed decisions about treatment plans.

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 data and medical 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 institution.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. See the information found under **"Will my data or samples be used for future research?"**

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the U.S. Office of Research Integrity (ORI), the U.S. Office for Human Research Protections (OHRP), and the U.S. Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Will my data or samples be used for future research?

This study is collecting data from you. We would like to make your data available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions,

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or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Your data and samples may be shared with researchers around the world. Our goal is to make more research possible. We plan to keep your data and samples for 5 years after study completion. To get your data or samples, future researchers must seek approval from this institution, and review by an IRB may be required.

Your name and identifying information will be removed from any data and samples you provide before they are shared with other researchers. Researchers cannot easily link your identifying information to the data and samples.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include severe medical illness preventing study completion or departure far from study site.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

If you become ill or are injured as a result of this study (medications, devices, or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you \$100 for every visit for a total of up to \$300 for your time and effort

You will have the option to receive cash or a gift card. The Accounting Services at Northwestern University will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are \$600 or more in a calendar year.

You will have access to study results at the end of the study after the data are locked and the data are presented, including your clinical scores.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations

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- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Billing information

During this study, you may be coming to a Northwestern Memorial HealthCare/Northwestern Medicine entity for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Genentech, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

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Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing.

To revoke your authorization, write to:

PI's Name: Farrah Mateen, MD, PhD
Institution: Northwestern Medicine
Department: Neurology
Address: Morton Building 7-643
310 E. Superior St.
Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company

Signature Block for Adults Capable of Providing Consent:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

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Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent