Introduction

You are being invited to participate in a research study to evaluate the quality of life in people living with Multiple Sclerosis (MS). Please read the description of the study detailed below and its risks and benefits before you decide if you would like to participate. Please take as much time as you need to make your decision; feel free to discuss this proposed study with anyone and ask the study staff to explain anything that you do not understand. Make sure that all your questions have been answered before signing this consent form. Participation in this study is voluntary.

Background and Purpose

MS is a common and often disabling disorder. Historically, when MS outcomes have been assessed, clinical outcomes, such as rates of relapse or degree of symptom reduction, were measured. More recently we have seen the increased utilization of alternate forms of outcomes assessment in clinical settings, such as the measurement of quality of life. Our research team will be using the MS-QoL-54, Quality of Life assessment, which has been used for over 25 years in people with MS.

Please note: This is a research study and is not intended to provide a medical diagnosis or treatment.

Participant Inclusion Criteria You may participate in this study if you:

1. are aged 18 or above.

2. have a diagnosis of Multiple Sclerosis

Study Procedures

If you agree to take part in this study, you will be given the Quality-of-Life tool, a 54-item questionnaire measuring quality of life. The questionnaire should take you between 15 to 20 minutes to complete.

Potential Risks

There are no risks or inconveniences anticipated regarding participation in this study. Your participation will not directly impact your current or future treatment and care for MS or your relationship with Vivo Infusion.

Potential Benefits

You may or may not benefit from this study. You may gain more knowledge and awareness about your own quality of life with MS, but no benefits are guaranteed. You will not receive any profits, legal entitlements, or other commercial benefits from the study.

Confidentiality

Your personal information will be respected and kept confidential. You will not be identified by name in any reports or products of the completed study. All printed documents will be identified by code numbers and retained by Vivo Infusion in a secured location with limited access. Unidentified (anonymous) data from this study may be combined with data from other studies to present findings from a larger group of participants.

Remuneration

You will not be paid for allowing your Quality-of-Life tool data to be used in this study.

Voluntary Participation/Ability to Withdraw

Your participation in this study is entirely voluntary. You may exit the Quality-of-Life study at any time and are under no obligation.

At a later date, you may be invited to participate in additional activities to evaluate future aspects of the Quality-of-Life tool. Please note that your participation in this study does not obligate you to participate in future evaluations.

Summary of Research Results

Any published results of these studies will be made available to you.

Conflict of Interest

There are no known actual, apparent, potential, or perceived conflicts of interest in conducting this study.

Questions or Concerns About the Study

For general questions, please scan the QR Code below to visit https://vivoinfusion.com/qolstudy/ for more information, including Frequently Asked Questions.

For specific questions about this study, please contact our Director of Clinical Trial Services, Dr. Robert Singh, by phone at 610.427.3841 or by email at **research@vivoinfusion.com**.

For compliance concerns, please email Francine Wachtmann, Chief Compliance Officer, at **fwachtmann@vivoinfusion.com.**

Consent

Quality of Life in MS Data You consent to participate in this study by fully reading this form and indicating YES to “I consent to include my data in research” on the Quality-of-Life tool. I have read and understand the subject information and consent form of this study.

· I freely consent to participate in this study.

· I have had sufficient time to consider this information and to ask for advice if necessary.

· I have had the opportunity to ask questions and have received satisfactory responses.

· I understand that my identity will be kept strictly confidential, and that the information collected will only be used for scientific objectives.

· I understand that my participation in this study is voluntary and that I am completely free to refuse to participate, or to withdraw from this study at any time, without changing in any way the care that I receive.

· I understand that I am not waiving any of my legal rights by signing this consent form.

· I understand that there is no guarantee that this study will provide any benefits to me.

· I understand that I will receive a dated and signed copy of this form to keep for myself.

· I understand that this is a research study and will not provide medical diagnosis or treatment.

Participant’s Printed Name	
Participant’s Signature	
Date (mm/dd/yyyy)	
Legal Representative’s Printed Name	
Legal Representative’s Signature	
Date (mm/dd/yyyy)	
Witness to Consent (Vivo) Printed Name	
Witness to Consent (Vivo) Signature	
Date (mm/dd/yyyy)	

IMPORTANT

one signed original to be kept in Researcher QoL study file

one signed copy to be given to the Participant and/or Participant's legal representative

one signed copy to be kept in the clinic file