Queen Square MS Centre - UCL Institute of Neurology

Investigator: Professor Richard Nicholas

Centre Number:

Contact for Queries:

If you have any questions about this study, you can contact:

Daytime: 02031081955

Out of hours (emergency): 07970479797

The National Hospital for Neurology & Neurosurgery
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WC1N 3BG

Consent Form for the Simvastatin in PMS Study (MS-OPT)

Sponsor Reference number: 16/0730

Version 1.3 dated 08/09/20

Study title: A double-blind, randomised, placebo-controlled single site study of high dose simvastatin treatment for progressive multiple sclerosis: impact on vascular perfusion and oxidative damage.

Name of Researcher (PI):	
Sponsor Study Number:	16/0730
Site:	
Participant Number:	

		Please initial each box
1.	I have read and understood the patient information leaflet (version 1.4 dated 08 Sept 2020) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation in this study is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my medical care or legal rights being affected.	
3.	As described in the study information leaflet, I understand that sections of my medical notes may be looked at by responsible individuals from CCTU, institutions acting on their behalf or regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	
4.	As described in the study information leaflet, I understand that **non identifiable** data collected in the study may be sent to third parties (e.g. pharmaceutical companies or other academic institutions) for research, safety monitoring or licensing purposes and that this may involve some data being transferred within the European Union.	
5.	As described in the study information leaflet, I agree to complete the study assessments including MRI and retinal imaging (scans of the eye).	

6.	As described in the study information leaflet, I agree to my GP and/or consultant being informed about my participation in the study.	
7.	As described in the study information leaflet, I agree to having my blood sample stored for the purpose of future research for up to 10 years from the date of my consent.	
8.	If I or my partner becomes pregnant whilst I am on this study, I understand that my doctor will inform the treating obstetrician of my involvement in this study and that the obstetrician may be requested to provide relevant information regarding the pregnancy and or birth. I understand that this may involve requesting access to my medical records and that anonymised information relating to the pregnancy or birth may be reported to the sponsor, ethics committee or regulatory authorities. I give permission for these individuals to have access to my medical records.	
9.	I freely agree to take part in this study.	

Please print and sign your name below and add today's date:

_____	_____	_____
Name of patient	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date

N.B. The patient must date his/her own signature

1 original copy in study file; 1 copy for patient; 1 copy to be kept with hospital/clinic notes.