[Trust Logo]

Methotrexate Oral Or SubcutanEous for RA

The **MOOSE** Study

IRAS ID: 1006576

Informed Consent Form

Version 1.0 28 Apr 2023

IRAS Project ID		**Site Name**	
Site No.		**Principal Investigator**	

Name of Participant	
Participant Trial ID **(To be completed after randomisation)**	

		Please initial box
1.	I confirm that I have read and understand the Participant Information Sheet, Version <insert current PIS version number> 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 is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw, then the information collected so far cannot be deleted and that this information may still be used in the trial analysis.	
3.	I understand that relevant sections of my medical records and data collected in the trial may be looked at by authorised individuals from the Nottingham Clinical Trials Unit (University of Nottingham), the Sponsor (University of Nottingham), NHS bodies, the trial research group (Keele University and the University of Sheffield) and regulatory authorities where it is relevant to my taking part in this trial. I give permission for these individuals to have access to these records and I understand that my personal details will be kept confidential.	
4.	I give permission for a copy of this signed consent form to be sent to and be retained by the Nottingham Clinical Trials Unit.	
5.	I understand that additional blood samples may be taken at baseline and week 24 for the purpose of this trial and research associated with this trial. This sample will be tested at the local hospital(s) that I attend for the treatment of my rheumatoid arthritis. I agree to the collection, storage and destruction, and analysis of this sample as per usual practice in my local NHS hospital.	
6.	I give permission for the Nottingham Clinical Trials Unit, the Sponsor, and the trial research group to collect, store, analyse and publish information obtained from my participation in this trial.	

7.	I understand that the information held and maintained by my GP may be used to help contact me, or provide information about my health status for the purpose of obtaining follow-up information if I do not return completed study documents as requested .	
8.	I agree to my GP being informed of my participation in this trial. Should I become pregnant whilst I am taking part in the MOOSE study, I agree to my GP being informed of the pregnancy.	
9.	I agree to take part in the above trial.	

		Please initial either box	
	Optional *The following are optional, and you can still take part in the study if you answer "No"*	**Yes**	**No**
12.	I would like to receive a summary of the results at the end of the MOOSE study by post or email.		
13.	I agree for my medical records to be reviewed to obtain data for a 2 year follow up.		
14.	I agree to be contacted via telephone regarding treatment acceptability discussions.		
15.	I understand that my name and telephone number will be held by Esendex (text messaging service provider) and their subprocessors and will be used to send me text message reminders about the study and study questionnaires. I give permission for this information to be retained by Esendex, even if I withdraw from the study, for two years or until the end of the study (whichever occurs first).		

Name of Participant	Date	Signature
	D D - M M M - Y Y Y Y	

Name of person taking consent	Date	Signature
	D D - M M M - Y Y Y Y	

(You must be on the delegation log and authorised to perform this task)

ICF copies to be retained by: Participant (personal copy), Site (Patient medical notes), Investigator (uploaded to trial database).