IRAS ref: 17/SC/0556

Multicentre Observational Intervention assessing Treat to Target Outcomes in Psoriatic Arthritis (MONITOR-PsA)

Principal Investigator details: Dr Laura Coates

MAIN: CONSENT FORM -

Title of Project: A multicentre observational psoriatic arthritis cohort study addressing real-life outcomes of a treat to target approach in routine clinical practice.

Participant Initials				**Participant No.**		**Site Code**	

		Please write your initials in the each of the boxes below if you agree
1	I confirm that I have read and understand the information sheet V……. dated ……/……./……for the above study, that I have had the opportunity to ask questions and that I have received satisfactory answers to the questions that I have asked.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3	I understand that sections of any of my medical notes may be looked at by responsible individuals from the Sponsor, regulatory authorities and Host NHS organisations where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	☐
4	I understand that a copy of my details will be sent to the study coordinating team in Oxford using secure encrypted electronic transfer. These details may be used to check contact details using NHS Digital and other central UK NHS bodies, and to provide other basic study-related information that may be needed for follow up. This will allow the study team to contact you if you miss a clinic visit.	☐

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OPTIONAL:

Use of data:

You can agree to clauses 1 and/or 2, below:

Please initial one box under Yes or No

		YES	NO
1	I agree for my personal information to be stored confidentially and securely by the study team, with linked pseudonomysed clinical and genetic data (including from any samples I give), so that they can contact me in the future to invite me to participate in any research studies related to my condition.	☐	☐
2. a)	I understand that the study team may make a random selection of some participants and invite those individuals to participate in the treatment arm of other research studies of treatment (including clinical trials of medicines).	☐	☐

Giving of samples:

If you do agree to give samples, we would ask that you agree to all of the clauses in this section.

3	I agree to donate blood, urine and faecal samples at each assessment.	☐	☐
4 a)	I understand that these samples will be used in genetic and biomarker research, aimed at understanding the genetic influences of diseases. However, the results of these investigations are unlikely to have any implications to me personally.	☐	☐
4 b)	I agree that any blood samples I donate for the study will be considered a gift to the University of Oxford and I understand I will not gain any direct personal or financial benefit from them.	☐	☐

Future use of samples:

If you do agree to give samples, the below clauses are regarding their future use. If you are happy for them to be used in future research, we would ask that you agree to all of the clauses in this section.

5 a)	I agree for my anonymised samples to be used in future research, here or abroad, which has ethics approval. I understand this research may involve commercial organisations, although I will gain no personal or financial benefit from this.	☐	☐
5 b)	I further understand that samples of DNA and RNA may be extracted for research aimed at understanding the genetic influences on disease and that the results of these investigations are unlikely to have any implications for me personally.	☐	☐

Ooms A, *et al. BMJ Open* 2023; 13:e078539. doi: 10.1136/bmjopen-2023-078539

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_____ _____ _____

Name of Patient Date Signature

(Please print your name and date your own signature)

_____ _____ _____

Name of Person taking consent Date Signature

(Investigator/delegated medically – qualified sub investigator)

Original copy – site file

1 copy for patient; 1 copy to be kept with hospital notes; 1 copy for TMF at Co-ordinating centre.

Ooms A, *et al. BMJ Open* 2023; 13:e078539. doi: 10.1136/bmjopen-2023-078539