Barts and The London
Queen Mary's School of Medicine and Dentistry

Barts Health NHS
NHS Trust

Patient Consent Form - Version 10 Dated: 29th June 2021

Title of project: Pathobiology of Early and Established Arthritis Cohorts (PEEAC)

Investigator: Prof. C. Pitzalis REC study No. 05/Q0703/198 IRAS ID: 60271

Centre Number: REC Study Number: **05/Q0703/198** IRAS ID**: 60271**

Patient Identification Number for this trial:

Please initial each box to indicate agreement

1.	I confirm that I have read and understand the information sheet **dated 29th June 2021 (version 10)** 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, without my medical care or legal rights being affected.	
3.	I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from regulatory authorities or from the Queen Mary University of London, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4.	I realise that I will not receive any personal financial reward for donating the samples that I have gifted to the research team	
5.	I understand that some tissue samples may be sent to our collaborators in the UK and worldwide, including the USA	
6.	I agree to tissue samples being used for future, currently unforeseen, medical research projects in the UK and worldwide, including the USA	
7.	I agree to my GP being informed of my participation in the study.	
8.	*Optional Consent for genetics/DNA research* I agree to have the genes that my cells carry studied for research. **Please tick Yes or No:** Yes ☐ No ☐	
9.	I agree to take part in the above study.	

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from Investigator)	Date	Signature
_____	_____	_____
Investigator	Date	Signature

1 copy for Patient, 1 for Investigator and original to be kept in medical notes

Patient Information Sheet - Version 10 Dated 29th June 2021

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1. **Invitation paragraph**

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.
Thank you for reading this.

2. What is the purpose of the study?

Inflammatory Arthritis is an important chronic condition that is responsible for significant disability and loss of quality of life in many of those affected. The purpose of the study is to understand the mechanisms that lead to joint inflammation, destruction and, to patient disability. The aim is to better link disease symptoms with biology in order to understand the underlying disease mechanisms and develop better ways to guide treatment decisions.

3. **Why have I been chosen?**

The reason why you have been chosen is because you have arthritis. This is the result of inflammation which has begun to affect the lining of the joints. We are interested in how this inflammation will affect the joint itself and the lining. We also need to study which genes are carried, and which are switched on or off in the cells of the joint however your consent to this is optional. Opting out of this will not affect your participation in all other aspects of the study or your routine management of arthritis. Examination of tissue from the lining of your joint will give enormous information on how this process occurs and how it is influenced. To do this we will use the same ultrasound machine that we used to show the inflammation in your joints to guide, following local anaesthetic to make the procedure painless, a miniature pair of tweezers (2mm thick, the thickness of a pencil lead) or a very small needle to take samples of the lining through a keyhole cut (of the same size, 2mm). Samples from finger joints use a special, even smaller (1.5mm) biopsy needle to obtain tiny samples. These samples will be analysed at the Centre for Experimental Medicine and Rheumatology, Queen Mary University of London, and may be sent to research groups and biotechnology companies with whom we work in the UK and worldwide, including the USA, but only if they have agreed to collaborate under the terms of this study.

4. **Do I have to take part?**

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

5. **What will happen to me if I take part and what do I have to do?**

If you decide to take part, there would be no change whatsoever in the normal management of you and your condition in an out-patient setting. You will continue to attend clinic every three months and receive a clinical assessment of your disease activity. The only difference would be, as mentioned above, that we would seek your permission to perform a procedure whereby a needle would be inserted into an inflamed joint under ultrasound guidance and a sample of tissue (small biopsies) from the lining of the joint would be removed. This procedure would be performed under local anaesthetic, normally this is very well tolerated but rarely this maybe complicated by infection of the joint (0.1%); wound infection (0.1%); haemarthrosis (bleeding into the knee joint) (0.9%);

deep venous thrombosis (0.2%); neurological damage (0.02%); thrombophlebitis (inflammation of a superficial vein)

(0.08%). If an appropriate, we may perform a biopsy on more than one joint. This is to compare the process of inflammation between the different joints. At the 6 month time point you will be asked to consent again to undergo a biopsy procedure on one joint only. This is optional and your care will not be affected if you choose not to have a biopsy at the 6 month time point. During the procedure fluid from the joint will be retained for scientific analysis. This fluid would otherwise be discarded.

If you are diagnosed with a type of Arthritis involving your skin known as Psoriatic Arthritis we will perform a skin biopsy at baseline, to investigate whether differences in biological make-up within joints and skin of different PsA sufferers are related to arthritis disease severity.

We would also request you permission to take a blood sample and urine specimen at each of your clinic visits for research purposes. An ultrasound examination of your joints will also take place every 3 months. This non-invasive procedure will give valuable information about the activity of your arthritis, and maybe helpful in developing better treatment algorithms in the future for patients with early inflammatory arthritis. We would seek your permission to collect this data during your participation of the study.

During the course of this study you will be followed-up in the Rheumatology clinic according to best practice and as required by your clinical status.

6. **How will the information collected be kept confidential?**

The results of the research will be stored using study numbers so that your name will not be available to anyone other than the researchers involved. The computers being used to store your results are located within the hospital and are password protected. The data files regarding the study are also encrypted and password-protected. This provides a significant level of anonymity for you as the participant. However, for your own care, it will be possible for the research doctors within your clinical care team to link the results of the research tests back to you as an individual during the course of the study. In addition, laboratory researchers in our own or collaborating groups, your samples and results will be given a unique identification number, so that your name, medical record or other personal identifiers cannot be released or used in any publication or disseminated study information.

Queen Mary University of London is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Your hospital will keep identifiable information about you while the study is archived for 20 years. Queen Mary University of London will not hold any identifiable information about you.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your can find out more about how we use your information at http://www.jrmo.org.uk.

Your hospital will collect information from you & your medical records for this research study in accordance with our instructions.

Your hospital will keep your name, NHS number and contact details confidential and will not pass this information to Queen Mary University of London. Your hospital will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Certain individuals from Queen Mary University of London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Queen Mary University of London will only receive information without any identifying information. The people who analyse the information will

not be able to identify you and will not be able to find out your name, NHS number or contact details.

Barts Health NHS Trust will keep identifiable information about you from this study for 20 years after the study has finished.

7. **What are the possible benefits of taking part?**

There would be no clinical benefit directly to you for taking part in these studies. However, better understanding of the mechanisms that lead to joint damage may allow the development of new drugs thus may be of benefit to patients in the future. The results of these studies are likely to be published in medical journal and you would be most welcome to obtain a copy of the published research.

8. **Who is organising and funding the research?**

Research using your sample/s is funded by charitable organizations, for example Arthritis Research UK and the Medical Research Council and through an international research consortium: The Accelerated Medicines Partnership (AMP) supported by The National Institutes of Health in the USA that involves investigators from around the world including the UK, Europe and the USA,. A description of this additional study will be available on http://www.ClinicalTrials.gov, as required by U.S. law. It is important for you to understand that the utilization of your sample/s may have commercial value and the results generated may be of valuable intellectual property. If you decide to participate in these studies you agree to give your sample/s to the researchers who will be free to use your sample/s for academic and/or commercial research purposes. You will not own the results generated using your sample/s and you will not be entitled to any interest in or share of any profit that might arise from research using the sample/s.

9. **Who has reviewed the study?**

The studies have been reviewed by the National Research Ethics Service (NRES) London – Dulwich, (formerly the Research Ethics Committee of King's College Hospital, and City and the London.)

10. **Contact for Further Information**

If you would like further information please do not hesitate to contact Professor Costantino Pitzalis or the Rheumatology Research Team on 0208 223 8960/8828.

1 copy for Patient, 1 for Investigator and original to be kept in medical notes