

<u>Patient Consent form - Version 6 Dated: 11th September 2009</u>	
Title of project: <u>Pathobiology of Early Arthritis Cohort (PEAC)</u>	
Investigator: Prof. C. Pitzalis	LREC study No. 05/Q0703/198

Centre Number: Study Number: **05/Q0703/198** Patient Identification Number for this trial:

Please initial box to indicate agreement

1.	I confirm that I have read and understand the information sheet <u>dated 11th September 2009 (version 6)</u> 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 Barts and the London/ 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 agree to my GP being informed of my participation in the study.	
5.	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

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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?

The purpose of the study is to understand the mechanisms that lead to joint inflammation, destruction and, as a consequence, to patient disability.

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. Examination of tissue from the lining of your joint will give enormous information on how this process occurs and how it is influenced.

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 may be 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%). Permission for a second biopsy will be sought separately after 6 months. During the procedure fluid from the joint will be retained for scientific analysis. This fluid would otherwise be discarded. You will be free to decline such a biopsy if you so wish without affecting your care.

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 may be 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?

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

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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.

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. 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 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 (**insert contact name**) or a member of his/ her team – (**insert contact number**). Another source of information regarding participation in clinical studies is the Arthritis Support Group, Walter Newby Centre, Bethnal Green Methodist Church, Approach Rd, Bethnal Green, E2 9JX. Once again we would like to thank you for taking part in this study.