PLEASE PRINT ON HEADED PAPER

Patient Consent form (3rd Biopsy) - Version 2 Dated 10th November 2009

Title of project: Pathobiology of Early Arthritis Cohort (PEAC)

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 dated 10th November 2009 (version 2) 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/ Kings' College 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

PLEASE PRINT ON HEADED PAPER

Patient Consent form (3rd Biopsy) - Version 2 Dated 10th November 2009

Title of project: Pathobiology of Early Arthritis Cohort (PEAC)

Investigator: Prof. C. Pitzalis **LREC study No. 05/Q0703/198**

1. **Invitation paragraph**

   You have already agreed to take part in this clinical study and we have already performed two joint biopsies. We are now seeking your permission to perform a third joint biopsy for research purposes. 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 under go a third biopsy.

   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 and you have failed to respond, during the course of your treatment, to anti-TNF alpha therapy. This would indicate that you have an aggressive form of arthritis. We have previously performed two biopsies on your joints and now we are seeking permission to perform a third. The reason for this is that it would be important to establish the possible causes for this normally highly effective treatment to have failed in your case. It would be also important to establish whether this biopsy could provide information on the most appropriate treatment that we can give you next. The ability to target such new treatments to individual patients according to the characteristics of joint tissue inflammation would be a major therapeutic advancement in the treatment of rheumatoid arthritis.

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. The only difference would be, as mentioned above, that we would seek your permission to perform a third joint biopsy under ultrasound guidance and a sample of tissue 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%). 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. You will be followed-up in the Rheumatology clinic according to best practice and as required by your clinical status.

Patient Consent form (3rd Biopsy) - Version 2 Dated 10th November 2009

Title of project: Pathobiology of Early Arthritis Cohort (PEAC)

Investigator: Prof. C. Pitzalis **LREC study No. 05/Q0703/198**

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.

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 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.

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: 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.

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