BIOLOGICAL SUB-STUDY: PATIENT INFORMATION SHEET & CONSENT FORM

Investigator: Professor Paul Emery

Study Title: **CCP – Next Generation:** Co-ordinated Programme to Prevent Arthritis: Can We Identify Arthritis at a Pre-Clinical stage?

Functional characterisation of the genes and proteins involved in early RA (Bloods tests to study proteins involved in the control and activation of your immune system (including genetic material and DNA)

Protocol Number: RR17/93003

Study Sponsor: University of Leeds

Initials: _____ Subject No.: _____ Date of Birth: _____

You are being invited to take part in a sub-study to the main portion of the research study. Before you decide on participating, 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 or your GP if you wish. It tells you about the study and will answer some questions that you may have. Ask us if there is anything that is not clear or if you would like some more information. We want to be sure that you understand what the study is about.

You can find independent information on participating in clinical trials on the following web site: http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx. If you do not have access to the internet, or prefer a hard copy of the information, please ask the research doctor or nurse, who will be happy to provide you with one.

1. What is the purpose of the sub-study?

Many autoimmune diseases such as rheumatoid arthritis (RA) are associated with the presence of specific changes in an individual's genetic makeup. This can lead to changes in the proteins that are produced by these genes. We feel these changes may be important for the development of either the disease itself, specific antibodies or that they may even predispose to more severe disease. Sometimes new tests become available for help in diagnosing RA or predicting which patients may have more severe disease. We would like to store and freeze components of your blood (including DNA) for future studies. These samples will only be used in future studies that continue with this agreed line of research.

2. Why have I been chosen?

You have been asked to participate in the CCP-Next Generation study, which is a study following patients with new musculoskeletal symptoms or family members of patients with RA. The main part of the study involves testing for the presence of the anti-CCP antibody in the blood. As part of the study, at the same time as some of these blood tests we will ask you to donate additional blood samples which will be used solely for laboratory based research.

3. Do I have to take part?

You do not have to consent to having blood taken for this purpose (storage). If you do not wish to have this done, it will not affect your ability to enter the trial.

4. What will happen to me if I agree to take part in this sub-study?

- If you consent to take part in the sub-study you will have an additional 4ml (about 0.5 tablespoons) of blood drawn on your initial/screening visit.
- If you are a primary care patient and test negative for the CCP antibody, nothing more will be required from you as part of the sub-study.
- If you test positive for the CCP antibody, additional blood will be taken each time you come to clinic for the CCP – Next Generation study, the main study you have been told about: On your first visit, you will have an extra 90 ml of blood drawn (an amount equivalent to 6 tablespoons). On each of the other visits, you will have approximately an additional 50 ml of blood drawn (an amount equivalent 4 tablespoons). You will also be asked to provide a urine specimen.
- If you are a Control participant, and test negative for the CCP Antibody, an additional blood sample (3-4 tablespoons) will be taken at each study visit, which will be stored solely for future laboratory based research.

No blood will be drawn from you with out your permission and you may withdraw your consent or refuse at any time without penalty.

After the 48 weeks study period if you have not developed inflammatory arthritis you will be invited to continue attending the clinic annually or when clinically appropriate. A maximum of approximately 50 ml of blood will be drawn at these annual visits.

5. What will happen to my samples?

We will remove your personal details from all research samples after separation into their constituent parts. However, it will be possible to link the clinical and laboratory databases through a unique laboratory code to enable use to study long-term disease outcomes and response to future therapies you may receive. Your initials may also be collected as part of the code for the study.

In genetic studies we compare how often the gene(s) of interest are found in people with a disease to individuals that don't have it ("controls"). We would therefore like to store some of your DNA to form part of our "disease DNA bank" that we can use in our current and future genetic studies. This is purely for research purposes and you might not be told the results of the tests on your samples. The genetic information will be used solely for research purposes and may be shared with other research groups conducting similar investigations. This is because large numbers of individuals are required to undertake such genetics studies and they now need to be undertaken at the National or International level. Insurance companies, however, may ask you whether you have previously had genetic tests. Should this situation arise, we advise you to answer "no" in your insurance policy application form, as the tests carried out have no relevance to insurance.

If consent has been given, any samples that are not used at the end of this study will transferred to a Sample Repository and will be used in future studies within this research area.

6. What if I do not wish to take part?

All studies are always completely voluntary. If you do not wish to take part this will not affect any treatment you may receive. If you decide to take part you are free to leave the study at any time and without giving a reason. If you withdraw, unless you object, we will still keep the samples or data we already collected from you, as this is valuable to the study. A decision not to take part or to withdraw at a later stage will not affect your legal rights or any standard treatment you receive.

7. What will happen to the results of the research study?

When the study is complete the results from all the patients will be combined and will be published (without reference to your name or address) as a scientific paper. This paper may form part of a higher research degree being undertaken by one of the study doctors.

8. Who is organizing the research?

The Department of Rheumatology, University of Leeds are organising and responsible for the conduct of the study. The study doctor and nurse will not receive any payment for conducting this research study.

This study has been reviewed by the Leeds East Ethics Committee. This committee is appointed to determine that research studies are ethical and do not impair the rights or well-being of patients. We have received approval by this committee to be able to do this research study.

9. What will happen to my data?

The University of Leeds is the sponsor for this study based in the United Kingdom. We will be using information from you and/or 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. The University of Leeds will keep identifiable information about you for 15 years after the study has finished.

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.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

You can find out more about how we use your information [at URL and/or by contacting https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/02/Research-Privacy-Notice.pdf or can contact dpo@leeds.ac.uk

10. Will my taking part in this study be kept confidential?

Yes. If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper and electronically at Chapel Allerton hospital under the provisions of the Data Protection Act 2018. You will be allocated a trial number, which will be used as a code to identify you on all trial documents.

We will remove your personal details from all research blood samples before testing. Laboratory staff will not have access to any personal identifying information. However, during the study it will be possible to link the clinical and laboratory databases through a unique laboratory code by members of the research team. The laboratory staff performing tests will not have access to any of your personal details. If you decide to take part you are still free to withdraw from the study at any time and without giving a reason. This will not affect the standard of care you receive.

The genetic information, which contains your personal details, will be used only for research purposes and will not be shared with any other individual/s outside our research group. Insurance companies, however, may ask you whether you have previously had genetic tests. Currently, as these tests will be done as part of a clinical trial, these tests are “non-declarable” though this may change in the future. If you are unsure about the implications (if any) on your insurance, please discuss this with your insurance company.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

The NHS (GP Surgery and Leeds Teaching Hospitals Trust) will use your name, NHS number and contact details 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. Individuals from University of Leeds and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The NHS will pass these details to the University of Leeds along with the information collected from you and your medical records. The only people in the University of Leeds who will have access to information that identifies you will be people who need to contact you to regarding the study, to offer you future opportunities to participate in research, for your medical care or audit the data collection process. 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.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor (the University of Leeds), which is the organisation responsible for ensuring that the study is carried out correctly. Coded health information may be sent to other countries, some of which may not have the same level of personal data protection as within the United Kingdom. However, your name will not be passed to anyone else outside the research team or the sponsor.

We will remove your personal details from all research blood samples before testing. Laboratory staff will not have access to any personal identifying information. However, during the study it will be possible to link the clinical and laboratory databases through a unique laboratory code by members of the research team. The laboratory staff performing tests will not have access to any of your personal details. If you decide to take part you are still free to withdraw from the study at any time and without giving a reason. This will not affect the standard of care you receive.

We may share anonymised samples and clinical data collected in this study with regional, national and international collaborators who are conducting studies with similar research themes. Collaborations may be with other academic institutions and/or industry organisations. This will allow a greater range of technologies to be applied and help to facilitate specific research objectives

11. Contact names and numbers

If you need any further information please do not hesitate to contact your study doctor or nurse. You should also contact your GP for independent advice should you so desire.

Chapel Allerton Hospital

Drs Jackie Nam, Kulveer Mankia, Laurence Duquenne and Leticia Garcia

Monday to Friday 9am to 5pm:

- Research admin office Tel: (0113) 39 24734
- Research nurse office Tel: (0113) 39 24729

If calling after hours or in an emergency, please call:

- Ward C2 Tel: (0113) 39 24202

Thank you for taking the time to read the information.

The Leeds Teaching Hospitals NHS
NHS Trust

BIOLOGICAL SUB-STUDY: CONSENT FORM

(Functional characterisation of the genes and proteins involved in early RA)

Title of Project: CCP – Next Generation: Co-ordinated Programme to Prevent Arthritis: Can We Identify Arthritis at a Pre-Clinical stage?

SUB-STUDY: **bloods tests to study proteins involved in the control and activation of your immune system (including genetic material and DNA)** .

SUBJECT INITIALS: ☐☐☐ SUBJECT NO.: ☐ SUBJECT DOB: ☐☐☐

Please write your **initials** in the boxes below

1. I have read the patient information sheet (v3.0 dated 01.07.2021) for the above study. ☐
2. I have had the opportunity to ask question about the study and to discuss it with family, friends and/or GP. ☐
3. I understand the purpose of the study, and how I will be involved. ☐
4. I understand, and accept, that if I take part in the study I may not gain any direct personal benefit from it. ☐
5. I understand that all information collected in the study will be held in confidence and that, if it is presented or published, all my personal details will be removed. ☐
6. I give permission for responsible individuals from regulatory authorities to have access to my medical notes where it is relevant to my taking part in the research. This is on the understanding that no personal details which might identify me will be presented or published without my permission. ☐
7. I confirm that I will be taking part in this study of my own free will, and I understand that I am free to withdraw from the study at any time without giving a reason and without affecting my future care or legal rights. ☐
8. I agree to have genetic tests performed for research purposes. ☐
9. I understand that it may not be possible to withdraw my samples from the study once the collection of clinical data is complete. ☐

OPTIONAL

10. I agree to the blood samples being stored for future research in a HTA-licensed premise on the understanding that all projects will be independently reviewed by a Research Ethics Committee. ☐
11. I understand that my anonymised clinical samples and data may be shared with other research collaborators, outside the University of Leeds and may be used for future research. No personal information will be shared. ☐

Patient Signed……Date……

Patient Name (block capitals)……

Investigator/Delegated individual: I have explained the study to the above named patient and he/she has indicated his/her willingness to participate.

Signed……Date……..

Name (block capitals)……..