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UNIVERSITY OF OXFORD

PARTICIPANT INFORMATION SHEET

STUDY TITLE: Prevalence of Pathogenic Antibodies in Psychosis (PPiP)
You are being invited to take part in a research study. Before you decide if you want to take part, we would like to inform you about why the research is being undertaken. Please take time to decide whether you would like to take part. Please ask for clarification of any points and discuss it with others if you wish.

Thank you for reading this.

WHAT IS THE PURPOSE OF THE STUDY?
The study aims to understand if some cases of psychiatric illness are caused by immune system problems in some people. The immune system normally controls our ability to fight infection. If the immune system goes wrong it may cause diseases called 'autoimmune' diseases. We can diagnose some of these immune diseases using blood tests.

WHY HAVE I BEEN INVITED?
You have been referred to a psychiatric service. We are looking to study people from across the country with similar experiences to you.

DO I HAVE TO TAKE PART?
It is your decision whether you take part. You are free to withdraw. If you would like to take part, you will be given this information sheet to keep and be asked to sign a consent form. Your decision will not affect your treatment or standard of medical care provided.

WHAT WOULD HAPPEN TO ME IF I DID DECIDE TO TAKE PART IN THE STUDY?
We would ask you to:

1. Sign the consent form attached to confirm your participation in the study.
2. Have blood samples taken by your hospital doctor, researcher or GP. This can be done at the same time as any other blood tests you need to have.
3. Allow your clinical team to share details of your background and symptoms with us. This may require around 15 minutes of your time to collect these details.
4. If your blood sample is positive for any tested antibodies we may contact you to invite you to take part in a treatment study. We may also wish to

pass-on your details to other researchers who may ask you to attend for additional testing or investigations.

YOUR EXPENSES
We will pay you £10 to compensate for the time and inconvenience

WHAT WILL I HAVE TO DO?
You will spend around 15 minutes with a member of the research team asking you questions about your illness. You will have a 23 ml (approximately one and half tablespoon) sample of blood taken.

WHAT ARE THE DISADVANTAGES OF TAKING PART?
The only disadvantages are those of blood taking which could cause local discomfort and bruising. We will reduce this by combining the test with blood tests you would have anyway, whenever possible.

WHAT ARE THE ADVANTAGES OF TAKING PART?
The advantages are the possibility of a new diagnosis or more accurate monitoring of your current condition. Most immune diseases are treatable. So, if you did have a positive blood test, it would mean your doctor may suggest starting different treatment to help your symptoms.

WOULD MY TAKING PART IN THIS STUDY BE CONFIDENTIAL?
Yes, we will treat your clinical information with respect and confidentiality. All personal information recorded about you during the study will be kept confidential. All information will be stored securely in a locked filing cabinet and a secure database. Responsible members of the University of Oxford or the Oxford Health NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

WHAT WILL HAPPEN TO MY DATA?

We will be using information from you and your medical records in order to undertake this study. Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will not keep identifiable information about you. We will store the anonymised research data securely at the University of Oxford for 10 years after the end of the study.

The [*local NHS Trust*] will use your name, address and contact details, to contact you about the research study and make sure that relevant information about the study is recorded for your care. They will keep identifiable information about you from this study for over 3 years after the study has finished as we may need to contact you about other relevant studies (e.g. treatment trial) or to feed-back your clinical team

or GP about new available tests and their results that may have impact on your clinical care. Any research documents with personal information, such as consent forms, will be stored securely at the [*local NHS Trust]*.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/]
You can find out more about how we use your information by contacting the study team ppip@psych.ox.ac.uk

Anonymised data obtained in this study may be shared in future ethically approved research studies in the UK or internationally.

WHAT IF I DON'T WANT TO CARRY ON WITH THE STUDY?
You can withdraw from the study at any point, and any stored samples that can be identified as yours will be destroyed if you wish.

WHAT IF THERE IS A PROBLEM?
The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.. NHS indemnity operates in respect of the clinical treatment with which you are provided.

If you have a concern about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Dr Belinda Lennox (01865 613145, Belinda.lennox@psych.ox.ac.uk), or you may contact the University of Oxford Clinical Trials and research Governance (CTRG) Office on 01865 616480, or the head of CTRG, email; ctrg@admin.oc.ac.uk .

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.
If you wish to contact the PALS team please contact <*insert relevant NHS site phone number*> and email from the PALS website <*insert local PALS website*>

INVOLVEMENT OF YOUR GP AND PSYCHIATRIST
Your GP and psychiatrist will be notified of your participation in the study, if you agree to this.

WHAT WILL HAPPEN TO ANY SAMPLES I GIVE?
The blood sample (17 ml or approximately 1 tablespoon) that will be taken as part of this study is extra to clinical testing. Your blood samples and DNA would be assigned a code and your data would also be identified only by this number. The material

given to researchers would not have information that identifies you. However, your DNA is unique to you so it could never be completely anonymous.

With your consent, your samples will be indefinitely stored anonymously for use in future ethically approved research and genetic cell research studies.

They will be used mainly by local researchers, but ethically approved research projects may take place working together with other hospitals, universities, non-profit institutions or commercial laboratories worldwide.

PARTICIPATION IN FUTURE RESEARCH

If you agree, your personal details will be kept at the NHS trust where you are receiving mental health care so that they may be passed onto the study research team or other researchers who may invite you to participate in other ethically approved research studies for which you may be suitable (e.g. treatment study). Agreeing to be contacted does not oblige you to take part in future ethically approved studies.

WHAT WILL HAPPEN TO THE RESULTS OF THE WORK?

We will communicate all your blood test results to your referring doctor. The results of the study will be published in scientific journals and discussed at scientific meetings addressing both researchers and other patients with similar conditions. You will have full access to this. Your identity will be confidential, throughout.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The study is funded by the Medical Research Council. It is sponsored by the University of Oxford. Your doctor will not be paid for including you in this study.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East of England Research Ethics Committee.

CONTACT FOR FURTHER INFORMATION

Dr Belinda Lennox, or a member of the research team, may be contacted on telephone 01865 613145 , email ppip@psych.ox.ac.uk or by post at University of Oxford, Department of Psychiatry, Warneford Hospital, Headington, Oxford OX37JX.