<if applicable insert NHS organisation logo>

UNIVERSITY OF OXFORD

PARTICIPANT INFORMATION SHEET

STUDY TITLE: ***Prevalence of Pathogenic Antibodies in Psychosis 2 (PPiP2)***

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?

There is some evidence that some cases of psychosis may be caused by a specific problem with the immune system. The immune system normally controls our ability to fight infection. If the immune system goes wrong it may cause condition called 'autoimmune' diseases. We can diagnose some of these diseases using blood tests.

This study aims to see how many people with psychosis may have this specific problem with their immune system. We can find out that by testing your blood sample for specific antibodies.

If a problem with immune system is found, then you may be eligible to take part in a study called SINAPPS2.

WHY HAVE I BEEN INVITED?

You have been referred to a mental health service as possibly having psychosis or you are experiencing symptoms of psychosis . We are looking to study people from across the country with similar experiences to you. We are planning to recruit 6400 participants.

We would like to test a small blood sample from you in this study. If your blood test results indicate that your problems may be linked to your immune system, we may invite you to participate in a separate study called SINAPPS2. In the SINAPPS2 study we are testing a new treatment that may help people who have psychosis due to their specific problem with their immune system.

DO I HAVE TO TAKE PART?

It is your decision whether you take part. If you agree to take part, you are free to withdraw at any time without giving a reason. 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. If your blood sample was recently taken by your clinical team to test for neuronal membrane antibodies we may use it for the study.
3. Allow your clinical team to share details of your background and symptoms with us. We will collect details on your age, gender, ethnicity, previous history of psychotic illness, and length of current episode of psychosis symptoms from you and/or medical records. This may require around 15 minutes of your time to collect these details.
4. If your blood sample indicates this specific problem with immune system and if you agree, we may contact you to invite you to take part in a treatment study such as SINAPPS2. With your agreement we may also pass-on your details to SINAPPS2 trial 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 problems. 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?

You may/may not directly benefit from taking part in this study. However, if you did have a positive blood test, it would mean your doctor may suggest starting different treatment to help your symptoms as most immune diseases

are treatable. The advantages then are the possibility of a new diagnosis or more accurate monitoring of your current condition.

WOULD MY TAKING PART IN THIS STUDY BE CONFIDENTIAL?
Yes, we will treat your clinical information with respect and confidentiality. All personal information we collected during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

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 NHS organisation(s) 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. All identifiable information about you will be held securely at the <*local Organisation or the University of Oxford*>. Information that is sent out of the <*Organisation or the University of Oxford*> will have a study code instead of personal identifiers. We will store the de-identified research data securely at the University of Oxford for 10 years after the end of the study.

The <*local NHS Organisation*> 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 3 years after the study has finished as they may need to contact you about SINAPPS2 study and other relevant studies 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 Organisation*> and archived as per the <NHS *Organisation*> policy for medical notes retention.
If you agree to your samples being used in future research, your consent form will be held until the samples have been depleted or destroyed.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, 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 https://compliance.web.ox.ac.uk/individual-rights
You can find out more about how we use your information by contacting the study team ppip@psych.ox.ac.uk

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.ox.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 samples (up to 23 ml or approximately one and half tablespoon) that will be taken as part of this study is extra to clinical testing. Your blood samples 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.

We will test small amount of given blood sample in this study. With your consent and after testing for antibodies in this study the remaining samples will be indefinitely stored for use in (i) future ethically approved research and (ii) future genetic cell research studies. Your blood samples in future research

and DNA in future genetic cell research studies would be assigned a code and your data would also be identified only by this number. However, your DNA is unique to you so it could never be completely anonymous.

Your stored samples 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.
You can still ask for your samples to be destroyed at any time.

PARTICIPATION IN FUTURE RESEARCH
If you agree, your personal details will be kept separately from this study in a secure location at the NHS Organisation where you are receiving mental health care or the University of Oxford so that you can be invited to participate in SINAPPS2 study (treatment study) or other ethically approved research studies for which you may be suitable. Agreeing to be contacted does not oblige you to take part in any future studies and you can request that your contact details are removed from this register at any time. If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.

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 and Scotland A Research Ethics Committee.

CONTACT FOR FURTHER INFORMATION
<*insert local PI's name* >, or a member of the research team, may be contacted on telephone <insert *phone number*>, email *<insert PI's or local research team email>* or by post at <insert *local site's postal address*>.