<if applicable insert NHS organisation logo>

PARTICIPANT INFORMATION SHEET
WELFARE GUARDIAN /WELFARE ATORNEY/NEAREST RELATIVE

Study title: Prevalence of Pathogenic Antibodies in Psychosis 2 (PPiP2)

INTRODUCTION

We feel your ward/relative/person you are consenting for is currently unable to decide for himself/herself whether to participate in this research.

You are being invited to consider giving your permission for your ward/relative/person you are consenting for 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.

We would then ask that you put your own views about the research aside and consider and take into account what you know of their past and present wishes and feelings, had they been able to consent for themselves. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your ward/relative/person you are consenting for would have no objection to taking part we will ask you to read and sign the Consent Form for Welfare Guardian/ Welfare Attorney/Nearest Relative. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your ward/relative/person should be withdrawn.

If your decision is that your ward/relative/person you are consenting for would not wish to take part it will not affect the standard of care they receive in any way. If you are unsure about giving permission for your ward/relative/person you are consenting for to take part in this study you may seek independent advice. We will understand if you do not want to take on this responsibility.

Before you decide it is important for you to understand why the research is being done and what it will involve. The following information is the same as would have been

provided to your ward/relative/person you are consenting for. Please take time to read the following information carefully and discuss it with others if you wish. Please ask the research team if there is anything that is not clear or if you would like more information. 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 their blood sample for specific antibodies.

If the problem with immune system is found, then your ward/relative/person you are consenting for may be eligible to take part in a study called SINAPPS2.

WHY HAVE THEY BEEN INVITED?

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

We would like to test a small blood sample from them in this study. If their blood test results indicate that their problems may be linked to their immune system, we may invite them 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.

However, they currently lack the capacity to make an informed decision about whether they can take place in a research study. We are therefore asking you as their Welfare Guardian/Welfare Attorney/Nearest Relative, if you will give consent on their behalf to join this study. This is permissible under the Adults with Incapacity (Scotland) Act 2000.

WHAT WOULD HAPPEN IF THEY DID TAKE PART IN THE STUDY?

1. We will ask you to sign the Consent Form for Welfare Guardian/Welfare Attorney/Nearest Relative.

2. They will have a blood sample taken by their hospital doctor, GP or qualified researcher. The sample will be taken, if possible, at the same time as any other blood tests they need to have. If their blood sample was recently taken by their clinical team to test for neuronal membrane antibodies we may use it for the study.

3. Their clinical team will share details of their background and symptoms with the research team. We will collect details on their age, gender, ethnicity, previous history of psychotic illness, and length of current episode of psychosis symptoms from them or medical records. This may require around 15 minutes of your time to share these details if you know them.

4. If their blood sample indicates this specific problem with immune system and if they agree, we may contact them later to invite them to take part in a treatment study such as SINAPPS2.

THEIR EXPENSES

We will pay your ward/relative/person you are consenting for £10 to compensate for the time and inconvenience.

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 your ward/relative/person you are consenting for would have anyway, whenever possible.

WHAT ARE THE ADVANTAGES OF TAKING PART?

Your ward/relative/person you are consenting for may/may not directly benefit from this study. However, if they did have a positive blood test, it would mean their doctor may suggest starting different treatment to help their symptoms. Most immune diseases are treatable. The advantages then are the possibility of a new diagnosis or more accurate monitoring of your ward/relative/person you are consenting for's current condition.

WOULD THEM TAKING PART IN THIS STUDY BE CONFIDENTIAL?

Yes, we will treat their 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 their privacy at every stage.

All personal information recorded about them 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 THEIR DATA?

We will be using information from them and their 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 their information and using it properly. We will use the minimum personally-identifiable information possible. All identifiable information about you or your ward/relative/person you are consenting for will be held securely at <*the local NHS organisation or the University of Oxford*>. Information that is sent out of the NHS Organisation and the University of Oxford will have a study code instead of personal identifiers. We will store this 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 or your ward/relative/person you are consenting for's name, address and contact details, to contact you or the patient about the research study and make sure that relevant information about the study is recorded for their care. They will keep identifiable information about you and the patient from this study for 3 years after the study has finished as they may need to contact them about SINAPPS2 study and other relevant studies or to feed-back their clinical team or GP about new available test and their results that may have impact on their 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 <*local NHS organisation*> policy for medical notes retention.

If you advise that they would like their samples being used in future research, their consent form will be held until the samples have been depleted or destroyed.

Data protection regulation provides people with control over their personal data and how it is used. When you agree to your ward/relative/person you are consenting for information being used in research, however, their rights to access, change, or move their personal information may be limited, as we need to manage their information in specific ways in order for the research to be reliable and accurate.

Further information about their rights with respect to their personal data is available at

https://compliance.web.ox.ac.uk/individual-rights
You can find out more about how we use their information by contacting the study team ppip@psych.ox.ac.uk

WHAT IF THEY DON'T WANT TO CARRY ON WITH THE STUDY?
They can withdraw from the study at any point, and any stored samples that can be identified as theirs will be destroyed if they wish. You can also withdraw them from the study at any point without their care being affected in any away.

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

If you have a concern about any aspect of the way in which your ward/relative/person you are consenting for has 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 Advice and Support Service (PASS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care they receive as an NHS patient. PASS is unable to provide information about this research study.

If you wish to contact the PASS team please contact <insert relevant NHS site phone number and email from the PASS website <*insert local PASS website*>

INVOLVEMENT OF THEIR GP AND PSYCHIATRIST
Their GP and psychiatrist will be notified of their participation in the study, if you agree to this.

WHAT WILL HAPPEN TO ANY SAMPLES THEY GIVE?
The blood sample (up to 23 ml or approximately one and half tablespoon) that will be taken as part of this study is extra to clinical testing. Their blood samples would be

assigned a code and their data would also be identified only by this number. The material given to researchers would not have information that identifies them.

We will test small amount of given blood sample in this study. After testing for antibodies in this study, we would like to store in de-identified form the remainder of their samples for indefinite time for use in (i) future ethically approved research and (ii) genetic cell research studies. After your ward/relative/person you are consenting for regains their capacity we will seek their continued consent to store these samples. Their blood samples in future research and DNA in future genetic cell research studies would be assigned a code and their data would also be identified only by this code. However, their DNA is unique to them so it can never be completely anonymous.

Your ward/relative/person you are consenting for's 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 or your ward/relative/person you are consenting for can still ask for their samples to be destroyed at any time.

PARTICIPATION IN FUTURE RESEARCH

If you give permission that your ward/relative/person you are consenting for would be happy to participate in future research, their personal details will be kept separately from this study in a secure location at the NHS Organisation where they are receiving mental health care or at the University of Oxford. After they regain their capacity we will ask whether they would be willing to be approached about other research. If so, we will retain these details in order to invite them to participate in SINAPPS2 trial or other ethically approved research studies for which they may be suitable. Agreeing to be contacted does not oblige them to take part in future ethically approved studies and you can request that their contact details are removed from this register at any time. If you give permission to your ward/relative/person you are consenting for details being held to be contacted regarding future research, we will retain a copy of your consent form until such time when they consent themselves or their details are removed from our database but will keep the declaration form and your details separate.

WHAT WILL HAPPEN TO THE RESULTS OF THE WORK?

We will communicate all their blood test results to the 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. They will have full access to this. Their 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. Their doctor will not be paid for including your ward/relative/person you are consenting for 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 participants' interests. This study has been reviewed and given favourable opinion by the East of England REC and Scotland A Research Ethics Committee. NHS management approval has also been obtained.

CONTACT FOR FURTHER INFORMATION

If you have any further questions about the study please contact: Dr <*insert local P's name*>, or a member of the research team, may be contacted on telephone <*insert telephone number*>, email <*insert PI's or research team email address*>, or by post at <*insert local site postal address*>.

Thank you for taking the time to read this information sheet.