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Study title: Prevalence of Pathogenic Antibodies in Psychosis (PPiP)

INFORMATION FOR CONSULTEE

INTRODUCTION

We feel your relative/friend is currently unable to decide for himself/herself whether to participate in this research.

To help decide if he/she should join the study, we'd like to ask your opinion whether or not they would want to be involved. We'd ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the consultee declaration on the last page of this information leaflet. 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informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your friend/relative would not wish to take part it will not affect the standard of care they receive in any way. If you are unsure about taking the role of consultee you may seek independent advice. We will understand if you do not want to take on this responsibility.

The following information is the same as would have been provided to your relative/friend.

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 THEY BEEN INVITED?

They have been diagnosed with a psychiatric illness. We are looking to study people from across the country with psychiatric illness.

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

We would ask your friend/relative to:

1. Have a blood sample (23 ml) taken by their hospital doctor, GP or qualified researcher. This can be done at the same time as any other blood tests they need to have.
2. Allow their clinical team to share details of their background and symptoms with the research team. This may require around 15 minutes of their time to collect these details.
3. If their blood sample is positive for any of tested antibodies we may contact them about taking part in a treatment study. We may also wish to pass-on their details to other researchers who may ask them to attend for additional testing or investigations.

THEIR EXPENSES

We will pay your friend/relative £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 friend/relative 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 friend/relative's current condition. Most immune diseases are treatable. So, if they did have a positive blood test, it would mean their doctor may suggest starting different treatment to help their symptoms.

WOULD THEM TAKING PART IN THIS STUDY BE CONFIDENTIAL?

We will treat their blood and clinical information with respect and confidentiality. All personal information recorded about them during the study will be kept confidential. Their personal data will remain in the UK. All information will be stored securely in a locked filing cabinet and a secure database. If this work is published (in scientific journals or other communications), their identity would not be disclosed. 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 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. We will not keep identifiable information about

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

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 http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/
You can find out more about how we use their information by contacting the study team ppip@psych.ox.ac.uk

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

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.

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 your friend/relative 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.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 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 (17 ml) that will be taken as part of this study is extra to clinical testing.

Their blood samples, and DNA 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. However, their DNA is unique to them so it can never be completely anonymous.

With your consent, their samples will be stored anonymously for indefinite time 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
Their personal details will be kept at the NHS trust where they are receiving mental health care. Their contact details may be passed onto the study research team or other researchers who may invite them to participate in other ethically approved research studies for which they may be suitable (e.g. treatment study). Agreeing to be contacted does not oblige them to take part in future ethically approved studies.

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 friend/relative 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 the Norfolk 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 the University of Oxford, Department of Psychiatry, Warneford Hospital, Headington, Oxford OX37JX.