**PANTHER**

**Professional Legal Representative**

**Information Sheet Summary**

## Precision medicine Adaptive Network platform Trial in Hypoxaemic acutE respiratory failure

PANTHER is a clinical trial looking at treatments for critically ill adults who need organ support with conditions such as ARDS or during a pandemic. We are also investigating whether the hypo/hyperinflammtory subgroups respond to one these treatments better. There are different treatments available in this trial, these are described below.

You are being asked to provide your independent professional opinion and consent for someone who does not have capacity to do so. We would like to know if, in your opinion the patient has no objection to participating in this study and you see no reason why they should not be included in this study. As the patient does not have capacity to provide informed consent and a relative, friend, partner may not be available to provide their consent, we seek your professional opinion. Should the patient regain capacity, we will always seek their informed consent to ensure they are happy to continue to participate in the study after inclusion.

Thank you for reading this.

# WHAT TReatments are being tested?

We are testing treatments in patients who have been admitted to an ICU. Simvastatin and Baricitinib are treatments being compared against usual care for critically ill adults who need organ support. The patient will receive one of the treatments below or the standard of care if you consent to their participation. Further information on the treatments within this trial are provided below:

**Simvastatin**

Statins are commonly used to lower cholesterol and lower the risks of heart attacks or strokes. Simvastatin may help repair the lungs by reducing inflammation and repairing blood vessels in the lungs, therefore may be beneficial to treat critically ill adults who need organ support. This will be given for 28 days or up until the patient leaves ICU.

**Baricitinib**

Baricitinib is a medication used for arthritis. It reduces swelling and may also help repair the lungs by reducing inflammation. This will be given for 10 days or up until the patient leaves the ICU.

Not all treatments may be available at the patient’s hospital, their doctor will be able to tell them which treatments are available and best suited for them.

# WHAT WILL the patient need to do?

**Blood Tests**

To know if the patient is in the hypoinflammatory or hyperinflammatory group, we will take a blood sample. So that we can understand more about how the treatments in this study work, we will collect additional blood samples. Once they have been randomised, depending on the treatment, a second blood sample will be taken. Blood samples will also be collected 3 and 7 days later. Blood samples will usually be taken either via a line already in place or using a needle. About 30ml will be taken in total.

**Nasal Swabs & Tracheal Aspirate**

Patients will have a nasal swab to identify viral pathogens. Some participants will also have tracheal aspirate collected from the lungs.

These secretions are usually thrown away, but we will keep a small sample if you agree for the patient to take part in the study.

**Bronchoalveolar Lavage**

We may also take a fluid sample from the patient’s lungs using Bronchoalveolar Lavage (BAL). This will happen before they are randomised. Fluid samples will then be collected 3 and 7 days later. This helps us to know whether the treatment is working. This will not be performed if the consultant in charge of the ICU has any concerns whatsoever and will only take place if the patient is already intubated/on ventilation.

Before the patient leaves the hospital, we will ask them to complete some exercises and ask them some questions to see how well they can move around and how well they are able to understand and remember things. We’ll also find out how they are doing.

We may contact the patient at 3 and 6 months after they started in the trial with a telephone call or email to ask about their quality of life and wellbeing using questionnaires.

All patients, including those who do not wish to participate in PANTHER, will receive the best standard of care available at this hospital.

More information about this study including how we use patient data and privacy, legalities and insurance of the study, risks and benefits, how to make a complaint and how to find out the results of the study can be found in our patient information sheet. (A written copy is available or is available online at [www.panthertrial.org.uk](http://www.panthertrial.org.uk) )

# Who can I contact for independent research information?

***England/Wales sites only***

If you have any questions about being in a research study, you can contact the Trust’s Patient Advice Liaison Service (PALS). They will give you advice about who you can talk to for independent advice.

|  |  |
| --- | --- |
| **Local PALS office telephone number** | **Local PALS office address** |
|  |  |

***Northern Ireland sites only***

If you have any questions about being in a research study, you can contact the person listed below. They will give you advice about who you can talk to for independent advice.

|  |  |
| --- | --- |
| **Local Contact** | **Local address** |
|  |  |

***Scotland sites only***

If you have any questions about being in a research study, you can contact [*insert full name*] (contact details below) who is not involved in the study and will be able to give you independent advice.

[*insert independent contact telephone number/email address/postal address*]

If you are happy to proceed, please complete the attached consent form.

# Consent Form for PARTCIPANTS UNABLE TO GIVE CONSENT THEMSELVES

**PROFESSIONAL LEGAL REPRESENTATIVES**

**Full Title of Project:** Precision medicine Adaptive Network platform Trial in Hypoxaemic acutE respiratory failuRe - **PANTHER**

|  |  |
| --- | --- |
| **Site number:** |  |
| **Patient Number:** |  |
| **Patient Name:** |  |
| **Name of Principal Investigator:** |  |

**Please initial box**

|  |  |
| --- | --- |
| 1. I confirm that I have read and understood this document and have read/received a copy of the appropriate patient information sheet which includes a link to the privacy notice for **PANTHER.** |  |
| 1. I confirm I give consent for the patient to participate in the trial with the following treatments: Simvastatin, Baricitinib   (*delete treatments site is not participating in and strikethrough treatment if patient does not agree)* |  |
| 1. I confirm that I understand the **PANTHER** study and I have had the opportunity to ask questions which have been answered fully. |  |
| 1. I understand that I am giving this consent based on what I believe would be the person for whom I am providing consent’s wishes. In my opinion they would be willing to participate. |  |
| 1. I understand that their participation is voluntary, and I or the person I am consenting for are free to withdraw at any time, without giving any reason and without any legal rights nor treatment / healthcare being affected. |  |
| 1. I understand that sections of any of the patient’s medical notes and other personal data generated during the study may be looked at by responsible individuals from and working on behalf of Imperial College London, from NHS or by representatives of regulatory authorities, ICNARC, NHS Digital, SICSAG, from the NHS Trust where it is relevant to the patient taking part in this research. |  |
| 1. I give consent for information collected about the person whom I’m consenting to be used to support other research or in the development of a new test, medication, medical device or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure). |  |
| 1. I give consent for samples (bloods, nasal swab, lung secretions and fluids) collected about the person for whom I’m consenting to be used to support other research or in the development of a new test, medication, medical device or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure). |  |
| 1. I understand that tissue samples (bloods, nasal swab, lung secretions and fluids) and/or data collected from the patient are a gift donated to the research team and that I nor the person who I’m consenting will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication treatment, product or service. |  |
| 1. I agree to the patient’s tissue samples (bloods, nasal swab lung secretions and fluids) being used to undertake genetic research which may have the potential to generate data that can be tracked back to them. |  |
| 1. I give consent to allow the use the patient’s data that has already been collected in the trial, as well as ongoing data collection and follow up information to be obtained from their medical records up to 12 months after their inclusion. |  |
| 1. I agree to the patient’s GP being informed about their participation in this research study and any incidental findings to be conveyed to them (Optional). |  |
| 1. I agree that the person for whom I am giving consent will override my consent on their behalf if or when they are able to give informed consent themselves. |  |
| 1. I consent for the patient to take part in **PANTHER** |  |

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Name of Professional Legal Signature Date

Representative

*(not listed on the delegation log)*

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Name of staff member Signature Date

*(Listed on delegation log)*

The original is stored in the study site file, 1 copy for participant;

1 copy for hospital notes