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**PANTHER**

**Personal Legal Representative**

**Information Sheet Summary**

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

We are inviting critically ill adults who have been admitted to the intensive care unit (ICU) with certain conditions to be part of our research study. We are studying people who need organ support, such as with their lungs or heart with conditions such as Acute Respiratory Distress Syndrome (ARDS) or during a pandemic to participate. ARDS is a severe lung problem that makes it hard to breathe because there is too much fluid in the lungs. We know critically ill patients can be split into different subgroups called hypoinflammatory and hyperinflmmatory. We want to be able to identify which patient subgroups will respond best to a treatment in order to improve patient care. This form provides information on the study, the treatments we are using, and risks and benefits of taking part.

You are being asked to provide consent for someone who does not have capacity to do so. The patient, your relative, friend, partner is very unwell and as they do not have capacity to make an informed decision, we are asking you to act as their legal representative and make a decision on their behalf.

# 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 decide for them to participate. 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. One of these drugs, 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 up to 28 days or up until you leave the 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 you leave the ICU.

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*Both treatments are given as tablets to swallow. If the patient is unable to swallow, it will be given via a tube*

**Usual Care**

This will be the usual care provided at the local hospital.

Not all treatments may be available at the patient’s hospital, their doctor will be able to tell you which treatments are available and best suited for your friend/relative/partner. These treatment options listed above also include a ‘standard care’. A computer randomly selects which treatment options your relative/friend/partner will receive. This means they may not receive any of these treatments, even if you choose for them to participate in the PANTHER trial. How patients recover over time is then compared between the different treatment options to work out which treatments are best.

# Which treatments will they receive?

The treating doctor will decide whether your friend/relative/partner is suitable to participate in all or part of this trial.

# What else will the patient need to do?

A blue circle with white test tubes

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**Nasal Swab & Lung Secretion Test**

A nasal swab will be taken to find out whether the participant has any infections. Some participants will have secretions (tracheal aspirate) collected from the lungs. This is done with a small suction tube called a catheter. It is passed through a breathing tube and is part of your relative/friend/partners usual ICU care with the goal of keeping the lungs clear of secretions to help them breathe better.

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

**Blood Test**

To know whether 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 the patient has been randomised, depending on the treatment, a second blood sample will be taken. Blood samples will also be collected 3 and 7 days later (about 2 tablespoons total). Blood samples will usually be taken either via a line already in place or using a needle.

**Lung Fluid Test**

A blue circle with white lungs in it

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Lung Fluid Test

We may also take a fluid sample from the patient’s lungs. This procedure is called a Bronchoalveolar Lavage (BAL). This will happen before they are randomised. Fluid samples will then be collected 3 and 7 days later. This involves putting a thin flexible tube (bronchoscope) through their nose or mouth down into their lungs. This tube allows the team looking after them to see inside their lungs. Once in the right place, a small amount of saltwater will be poured into the lung and collected. This helps us to know whether the treatment is working. This is a well-recognised safe procedure often undertaken in ICU to look at lung inflammation. Extra sedation may be used and some local anaesthetic may be used to make the procedure is comfortable if needed. This procedure can rarely be associated with a fall in oxygen levels. Prior to inserting the bronchoscope the amount of oxygen will be increased and we will closely monitor these levels during the test. The test will be stopped if the oxygen level falls significantly. This will not be performed if the consultant in charge of the ICU has any concerns whatsoever and will only take place if your friend/relative is already receiving breathing support (called ventilation) via a breathing tube in the lungs.

Before your relative/friend/partner 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 will also collect data from their hospital records and other NHS linked data.

Once their treatment has finished, we may contact your relative/friend/partner 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 to check how they are doing. We may also collect this information using an electronic link (optional).

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

More detailed information about the 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 full patient information sheet and privacy notice. (A written copy is available or is available online at [www.panthertrial.org.uk/patients](http://www.panthertrial.org.uk/patients) )

# Site Contact Information

Investigator name:-

Site Contact details:-

Study Contact Information

Please contact The PANTHER Trial team using the following contact details:

Name: The PANTHER Trial Team

Telephone number: 0207 5949725 available during UK working hours Mon-Fri 09:00-17:00

Email: [pantheruk@imperial.ac.uk](mailto:pantheruk@imperial.ac.uk)

Website: [www.panthertrial.org.uk](http://www.panthertrial.org.uk)

Thank you very much for taking part in this study!

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

A copy of the written information and signed Informed Consent form will be given to you to keep.

# Consent Form for Participants Unable to give conesent themselves

**Personal Legal Representative** *(if in England/Wales/Northern Ireland)*

**Nearest Relative/Guardian/Welfare Attorney** *(if in Scotland)*

**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**

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| 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 my relative/friend/partner 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. They are free to withdraw at any time without giving any reason and without my legal rights nor treatment / healthcare being affected. |  |
| 1. I understand that sections of any of my relative/friend/partner’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, by representatives of regulatory authorities, ICNARC, NHS Digital, SICSAG, from the NHS Trust where it is relevant to my relative/friend/partner 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 from my friend/relative/partner 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 my friend/relative/partner 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 my friend/relative/partners 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 my friend/relative/partner being contacted about the possibility to take part in other research studies. |  |
| 1. I give consent to allow the use my friend/relative/partners 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 my friend/relative/partner’s GP being informed about their participation in this research study and any incidental findings to be conveyed to them (Optional). |  |
| 1. I understand my friend/relative/partner will be contacted by their local hospital or the study team in 3 and 6 months to ask about their quality of life and wellbeing.   *(if you agree to this statement provide their details below and tick their preferred contact method ).*  *Phone Email* |  |
| 1. I would like my friend/relative/partner to be informed of the PANTHER study results when these are available.   *(if you agree to this statement provide their details below).* |  |
| 1. I consent for my friend/relative/partner to take part in **PANTHER** |  |

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| Telephone number: |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Email address: |  | | | | | | | | | | | |  | |
| Postal address: |  | | | | | | | | | | | | | |

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Name of **Personal Legal Representative** Relationship to patient

*(If England/Wales/Northern Ireland)*

**Or Nearest Relative/Guardian/** *(If Scotland)*

*(amend accordingly)*

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Signature Date

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Name of staff member Signature Date

*(Listed on delegation log)*

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Name of witness Signature Date

*(To be used if PerLR cannot write*

*e.g. due to disability)*

*(Independent of PANTHER study team)*

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