**INVESTIGATOR SITE HEADED PAPER**

**Sepsis Trials in Critical Care - SepTiC**

*If in England/Wales/Northern Ireland*

**Personal Legal Representative - Information Summary and Consent Form**

*If in Scotland*

**Nearest Relative/Guardian/Welfare Attorney – Information Summary and Consent Form**

**What is it?**

SepTiC is a clinical trial designed to investigate treatments for sepsis. Sepsis occurs when the body is reacting to an overwhelming infection. This can cause damage to the tissue and organs in the body. Sepsis is a medical emergency that requires urgent treatment with antibiotics, fluids, and other drugs to improve oxygen flow to important organs and help the function of the heart. There are different treatments available for sepsis and in this trial, we want to know which treatments are best.

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 are the treatments?**

We are testing three different treatments in this study: -

1. Diagnostic Trial – this involves a PCR test that quickly tells us what bacteria may be causing the infection and may help us decide which antibiotics to give.
2. Fluid Trial – giving fluid is routine when treating sepsis, but there is no clear guide on how best to provide the treatment, we will test how much fluid should be given and if medication should be given to remove any build-up of extra fluid.
3. GM-CSF Trial – this drug can help the immune system fight infection by making more white blood cells.

These treatment options listed above also include a ‘standard care’ or ‘placebo’ option. A computer randomly selects which treatment options the patient receives. This means the patient may not receive any of these treatments, even if they participate in the SepTiC 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 and what do they need to do?**

The treating doctor will decide whether the patient is suitable to participate in all or part of this trial. A few extra blood tests may be taken (a couple of tablespoons) while they are in intensive care, usually from ‘drips’ already in place. They do not need to do anything for the study while they are in hospital. We will collect data from their hospital records and other NHS linked data. We may contact them 3 months later to see how they are and would like to contact them 6 months later with a short telephone call to ask about their quality of life, and wellbeing.

Participation into the SepTiC trial is voluntary. All patients, including those that do not wish to participate in SepTiC, 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.septictrial.co.uk](http://www.septictrial.co.uk))

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

**Site Contact Information**

Investigator name:-

Site Contact details:-

**Study Contact Information**

Please contact The **SepTiC** Trial team using the following contact details:

Name: The **SepTiC** Trial Team

24hr Telephone: 0207 5949725

Email: septic@imperial.ac.uk

Website: [www.septictrial.co.uk](http://www.septictrial.co.uk/)

Thank you very much for taking part in this study!

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 Consent Themselves**

**Full Title of Project:** Sepsis Trials in Critical Care - **SepTiC**

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

**Please initial box**

|  |  |
| --- | --- |
| 1. I confirm that I have read and understand this document and have read/received a copy of the appropriate patient information sheet and privacy notice for **SepTiC**
 |  |
| 1. I give consent for my relative/friend/partner to participate in the following trials:

Diagnostic and Fluid Trial  GM-CSF Trial |  |
| 1. I confirm that I understand the **SepTiC** 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 my relative/friend/partner’s medical notes may be looked at by responsible individuals from Imperial College London, from the NHS Trust or from regulatory authorities where it is relevant to their taking part in this research.
 |  |
| 1. I give consent for information collected about the person for whom I am giving consent to be used to support other research or in the development of a new test, medication, 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 (human tissue) collected about the person for whom I am giving consent to be used to support other research or in the development of a new test, medication, 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 and / or data collected are a gift donated to Imperial College and that I or the person I am consenting for will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, product or service.
 |  |
| 1. I give consent to being contacted about the possibility of my relative/friend/partner to take part in other research studies.
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| 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 to allow the use of data already collected by my relative/friend/partner in the trial, as well as ongoing data collection and follow up information to be obtained from my friend/relative’s medical records at 3, 6 months and 12 months after their inclusion.
 |  |
| 1. I agree that the medical records of the person for whom I am giving consent and other personal data generated during the study may be examined by representatives of the sponsor (Imperial College London), by people working on behalf of the sponsor, and by representatives of Regulatory authorities, ICNARC, NHS Digital and SICSAG where it is relevant to my relative/friend/partner taking part in this research.
 |  |
| 1. I agree to my relative/friend/partner’s tissue samples being used to undertake genetic research which may have the potential to generate data that can be tracked back to them.
 |  |
| 1. I agree to the person for whom I am giving consent taking part in the **SepTiC** study.
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Name of *(please insert from below)* Signature Date

*If England/Wales/Northern Ireland*

**Personal Legal Representative**

*If Scotland*

**Nearest Relative/Guardian/Welfare Attorney**

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Name of staff member Signature Date

*(Listed on delegation log)*

1 copy for participant; 1 copy for Principal Investigator 1 copy to be kept with hospital notes.

To ensure confidence in the process and minimise risk of loss, all consent forms must be printed, presented and stored in double sided format.