**Short Participant Information Sheet**

**Purpose**

This is a guide to the information to be provided to the patient if they indicate they may be willing to take part in this research study in order that they may give verbal consent to take part.

The provision of the information and the agreement from the patient to take part must be witnessed by another member of staff in the Emergency Department.

If the patient consents to take part in the study then please ensure the relevant informed consent form is completed.

Invite the patient to take part in the research study investigating whether early treatment with vasopressors is better than standard fluids used today.

**Why are they being asked to take part?**

* You have been asked to take part as you have been diagnosed with signs and symptoms of an infection (sepsis).
* The decision to take part is voluntary. You do not have to consent to being in this study to be treated for your infection. If you decide not to take part in this study then you will receive standard care.

**What is the aim of the study?**

* We are looking at comparing two different methods of treating sepsis. The standard care is to give IV fluids through a drip in your arm then adding a vasopressor medication. Vasopressors increases the blood pressure which allows a better blood flow to your vital organs. The alternative approach is to give the vasopressor medication straight away.

**What will happen to me?**

If you take part in the study, you will be assigned to one of two treatment groups at random (like tossing a coin).

* **Treatment 1 – Usual Treatment**

You will be given the normal treatment used in the UK for treating infections – a salt solution (balanced crystalloid) solution via a drip. You may have medication to increase your blood pressure (vasopressors) added at a later point, depending on your condition.

The medicine used in the intervention arm (norepinephrine) may harm an unborn child and women who are pregnant will not be able to take part in the study. A pregnancy test will be performed before any study treatment is administered in all women who could become pregnant. This includes women who routinely use contraception such as the combined oral contraceptive pill, have an intrauterine device (sometimes known as a ‘coil’) or who abstain from sexual intercourse.

* **Treatment 2 - Intervention**

If needed, you will have the medication to increase the blood flow to your vital organs (vasopressors) started immediately, via a drip in your arm. You may be given extra salt solution fluid through the drip in your arm later, if required.

Each treatment will be given for as long as they are required, but the trial treatment duration is 48 hours. Collection of data will stop after the 104 day follow-up period is complete. All other treatment will be decided by the doctor treating you, after discussing with you.

Once you leave the hospital we will look at your medical records between 31-44 days later and between 91-104 days later to see how well you have recovered and if you have been back to hospital for any further tests or treatment. We won’t need to contact you again to do this.

You will not need to come to hospital for any additional visits.

**What are the possible risks?**

* The risks of this clinical trial include many of the same risks that are associated with routine treatment of sepsis.
* Risks that could occur with study treatment are:
	+ Headache (mild)
	+ Shortness of breath (mild)
	+ Irregular heart rate (rare)
	+ Inflammation of infusion site

**Do I need to take part?**

* No you are free to withdraw your consent from the study at any time and your health care will not be affected in any way.

**What are the benefits of taking part?**

* Being in this study may be of no direct benefit to you but others may benefit from the results of this research in future.

**Will my taking part in this study be kept confidential?**

* Yes. Your personal health information, including your medical data will be collected by the study doctor and other site staff for this study’s research purposes and every effort will be made to ensure it is kept confidential.

**How will we use information about you?**

* In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.
* Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
* At the end of the study we will save some of the data in case we need to check it.
* We will make sure no-one can work out who you are from the reports we write.
* The information pack tells you more about this.

**What if something goes wrong?**

* The normal National Health Service Complaints mechanisms will be available to you.
* There are no payments made to participants
* There will be no compensation for you or your insurance company in the event of an injury

More detailed information about this study will be provided in a separate information and consent form that you will be asked to read and sign after your condition has stabilised, if you agree to continue with the study.

Contact your study doctor for questions about the research or injuries from the research at the number on the front of this form.