If you have any questions,
please contact:

<RESEARCH NURSE NAME>

Telephone: *<TO BE ADDED>*

Email: *<TO BE ADDED>*

or

<PRINCIPAL INVESTIGATOR NAME>

Telephone: *<TO BE ADDED>*

Email: *<TO BE ADDED>*

Thank you for taking the time to read this leaflet.

Please see the main Participant Information Sheet (Parent/Guardian) for full details of the study.

Endorsed by:

PICS

Coordinated by:

icnarc intensive care national audit & research centre

Research Ethics Committee
Reference Number: 16/LO/0854
IRAS Number: 195544

Parent/Guardian Information Leaflet

V1.2, 8 November 2016

<INSERT HOSPITAL/TURST LOGO HERE>

FiSh

Fluids in Shock (FiSh)

Pilot Study

NHS
National Institute for Health Research

What is the purpose of the study?

Children are now much more likely to survive any serious infection than ever before. This progress comes from a whole package of treatments including antibiotics, multiple rapid doses (boluses) of fluid (e.g. saline solution) into a child's veins ('fluid bolus therapy') and support for breathing and heart function. We hope to improve the outcome of children with a severe infection by refining one part of this package of treatment: by exploring *what is the best amount of fluid to give in the earliest stages of care.*

The aim of this study (called FiSh) is to find out whether children with symptoms of a severe infection, called septic shock, should be treated with fluid boluses which are smaller (10 ml per kg) than what is currently given (20 ml per kg).

Before embarking on a large clinical trial, it is important that we first assess whether it is possible to conduct such a trial.

This study aims to gather that information, in terms of finding out if the trial procedures work smoothly and looking at the views of parents and staff involved in the trial.

What will happen if I take part and what do I have to do?

Often with children who have a severe infection, fluid treatment must be given in an emergency. As your child needed fluids urgently, the doctors and nurses would not have had time to discuss this research study with you beforehand.

Your child would have been given an initial 20 ml per kg fluid bolus and then entered into the study. Your child was then given boluses of either 10 ml per kg or 20 ml per kg – this was randomly selected by a computer programme. We are seeking your consent to remain in the study as soon as it is practically possible.

All other aspects of care was the same and followed usual practice, irrespective of the assigned fluid amount.

The benefits and risks of receiving 10 ml per kg are unclear at this time – which is why this research is needed.

Ultimately this study will help to improve the future treatment of children with septic shock.

What information will be collected?

If your child takes part in the study, we will collect information regarding your child's progress in hospital from the medical notes.

All information collected will be kept completely confidential. At the end of the study, all identifiable information will be removed.

Do I have to take part?

Joining the study is entirely voluntary. You are free to leave the study at any time and this will not affect the standard of care you or your family member receives.

What next?

You may be approached about this study by a member of the emergency department or paediatric intensive care team.

An information sheet will be provided and a member of the team will go through this in detail with you.