TO BE PRINTED ON LOCAL TRUST HEADED PAPER

**INFORMATION SHEET FOR YOUNGER CHILDREN**

**Study Title**

**Eculizumab in Shiga-toxin producing E.Coli Haemolytic Uraemic Syndrome (ECUSTEC): A Randomised, Double-Blind, Placebo-Controlled Trial**

**Invitation to take part in this research study**

We would like to invite you to take part in our research study.

**Why have I been asked to take part?**

You have an illness called STEC HUS. We are asking your help to find out the best way to help children with STEC HUS to get better.

**Why is this project being done?**

We are trying to find out whether giving children two lots of eculizumab (a medicine) helps them get better from STEC HUS.

**What will happen to me if I take part in the research?**

The doctors and nurses will give you two injections of water into your vein, through a special straw (cannula). The first one will be in the next day or so and the second one will be in about a week. Because you are poorly at the moment you have probably already had the cannula put into your vein and they can use that one. The water might contain a medicine called eculizumab or might contain a harmless dummy medicine.

To make this as good a test as possible, no one will know whether you are having eculizumab or the dummy medicine until the test is finished. Everyone will have the same number of injections, but if you are having the dummy medicine, it won’t have any eculizumab in it.

Whether or not you are given eculizumab or dummy medicine will be decided by chance, rather like tossing a coin to get heads or tails.

Your care will be the same whether you have eculizumab or dummy medicine and we will be checking you closely.

You will have two more injections (probably in your leg) today or tomorrow and will need to take a medicine called an antibiotic for 8 weeks. These will help stop you getting a serious infection.

Children with STEC HUS have quite a few blood tests to see how they are getting on. We will use the results of these to see if eculizumab works. We would like to take some extra blood samples to help us understand more about STEC HUS. We’ll try to take these from the same needle when you are already having a blood test. We will use magic cream or spray – whichever you prefer. If you do not want to have an extra blood sample collected for the study that is okay, you can still take part in the study without giving these extra blood samples. We would also like to collect some samples of your wee.

We will ask your parents or carers to answer some questions about your quality of life (how happy you are feeling) at the beginning, middle and end of the study.

You will come back to see the study doctor 4 times after you leave hospital over the next year to check how you are getting on.

**Will joining help me?**

We cannot promise that the study will help you but the information we get might help treat young people with STEC HUS with better medicines in the future.

**Do I have to take part?**

**You do not have to take part in this test.** It is up to you. If you decide now or at any time that you do not wish to take part in this test, you will still get the best treatment available. If you take part, you can change your mind at any time without giving a reason.

**What if I don’t want to do the research anymore?**

If at any time you don’t want to do the research anymore, just tell your parents, doctor or nurse. They will not be cross with you. Your doctor will help you decide which medicine is best to use afterwards.

**Did anyone else check the study is okay to do?**

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. This study has been checked by the North East –Newcastle and North Tyneside 1 Research Ethics Committee.

If you agree to enter this test then you may be asked to sign a form to say that you agree along with your mum, or your dad, or your legal representative.

**Thank you very much for reading this.**

**You will be given a copy of this information sheet and a signed consent form to keep if you decide to take part in the study.**

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