



**TO BE PRINTED ON LOCAL TRUST HEADED PAPER**

**GDPR Addendum to the  
PARENT INFORMATION SHEET  
Version 1.0, 11<sup>th</sup> March 2019**

**Study Title**

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

**Study IRAS Number: 199217**

**Introduction**

This Addendum to the ECUSTEC Parent Information Sheet which you have already received provides new information following the introduction of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 on 25 May 2018. The new information is as follows.

**Additional Information**

The Newcastle upon Tyne Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom. The sponsor will be using information from you, your child, and your child's medical records in order to undertake this study and will act as the data controller for this study. This means that the sponsor is responsible for looking after your child's information and using it properly. The sponsor will keep identifiable information about your child from this study for up to 25 years after the study has finished.

Your rights to access, change or move your child's information are limited, as we need to manage your child's information in specific ways in order for the research to be reliable and accurate. If your child withdraws from the study, we will keep the information about your child that we have already obtained. To safeguard your child's rights, we will use the minimum personally-identifiable information possible.

Under the provisions of the General Data Protection Regulation (GDPR) 2018, you have the right to know what information the study coordinating office has recorded about your child. If you wish to view this information, or find more about how we use this information, please contact Legal Services at Legal Services, University of Birmingham, Edgbaston, Birmingham B15 2TT. Please note that a small fee may be payable to retrieve this information.

More information on how the University of Birmingham processes personal data can be found on the University of Birmingham's website on the page called 'Data Protection - How the University Uses Your Data'.

<Insert Trust name> will collect information from you, your child and your child's medical records for this research study in accordance with our instructions.

<Insert Trust name> will keep your child's name, NHS number and contact details to contact you and your child about the research study, and make sure that relevant information about the study is recorded for your child's care, and to oversee the quality of the study.

The information that will be provided to the sponsor and other organisations involved in this research is specified in the Parent Information Sheet.

<Insert Trust name> will keep identifiable information about your child from this study for up to 25 years after the study has finished.

All other aspects of the Parent Information Sheet, which you have already consented to, will remain in effect.

### **Where can I get further information?**

For queries about the study or for further information please contact:

Dr Sally Johnson, Telephone: 0191 282 4917 ECUSTEC Chief Investigator

<Insert Local PI Name>, Telephone <Insert Local PI Tel. No.>, ECUSTEC Principal Local Investigator

The ECUSTEC study co-ordinating centre is located at the Birmingham Clinical Trials Unit, Institute of Applied Health Research, Public Health Building, , University of Birmingham, Edgbaston, Birmingham B15 2TT. Tel 0121 415 9132, Fax: 0121 415 9135, Web address: [www.birmingham.ac.uk/ECUSTEC](http://www.birmingham.ac.uk/ECUSTEC).

**Please keep a copy of this addendum with the Parent Information Sheet and the signed consent form for the study.**