The ECUSTEC Trial

Samples

THE great north CHILDREN'S HOSPITAL

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

Dr Sally Johnson
Chief Investigator: ECUSTEC Trial

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

The ECUSTEC trial is supported by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR Partnership

Assessment visits - samples

- Day 30 stool sample
  - To determine whether Ecu leads to prolonged STEC excretion
  - Sent to Public Health England Microbiological Reference Laboratory
  - Upon discharge parent/participant should be provided with stool sample collection pot

ECUSTEC RESEARCH SAMPLE

FAO Dr. Claire Jenkins
Gastrointestinal Bacteria Reference Unit
Public Health England
61 Colindale Ave
NW9 5HT

In submitting this sample, you are confirming that consent for testing and possible storage has been given for research purposes.

Research Title:	**Eculizumab in Shiga-Toxin producing E. Coli Haemolytic Uraemic Syndrome (ECUSTEC): A Randomised, Double-Blind, Placebo-Controlled Trial**		
ISRCTN: 89553116 **REC Ref: 16/NE/0325**	**Sponsor Ref: 7837**	**EudraCT Number: 2016-000997-39**	**MHRA CTA: 17136/0282/001-0001**

Instruction to site

A stool sample should be obtained as close to the Day 30 assessment as possible, and brought to the clinic visit. The specimen tube and spatula, and the *ECUSTEC Stool Sample Collection –Instructions for Parents and Participants*, should be provided to the participant/ parent at discharge.

On return of the sample at Day 30, the sample pot should be labelled with the patient's, trial number, date of birth (month and year only), and the date of sample collection. Please complete the table below clearly in dark ink, then post the sample to the Public Health England Microbiological Reference Laboratory using the freepost packaging.

If the participant/ parent does not return a sample at Day 30, please ask them to obtain the sample within two days of the appointment and post direct to Public Health England using the freepost packaging. **Please add the participant trial number, the participant's full name and the sender's information below before giving this form to the participant/parents to take home. The participant/parent should add the date stool sample taken and date stool sent to PHE below once the sample has been taken.**

Participant Sample Details

Participant Trial Number (5 digits)	D.O.B.	Participant Full Name	Date Stool Sample Taken	Date Stool Sample Sent to PHE

Sender's Information

Sender's name and address:	Report to be sent to FAO: Contact phone number:

Instructions to Public Health England

Sample type and test required: **Detection of verocytotoxin-producing E. coli (VTEC) in faecal sample**.

Following receipt and processing of the sample, please email the ECUSTEC trials office (ECUSTEC@trials.bham.ac.uk) with the following information:

- Participant trial number
- Date sample received

Please forward all invoices to: Emma Barsoum (Trial Coordinator), Renal Trials Team, Birmingham Clinical Trials Unit, Institute of Applied Heath Research, College of Medical and Dental Sciences, Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT. Email: ECUSTEC@trials.bham.ac.uk

Please forward the result to the sender who will forward the result to BCTU.

Assessment visits - samples

- Week 52 Visit
  - A blood sample will be collected and sent to central laboratory for estimated GFR by creatinine and cystatin C
- Exploratory samples
  - Optional blood and urine samples to be collected
  - Day 1, 2, 4, 6, 8 and 30
  - If discharged between day 1 and day 8 participant is not required to return for urine and blood samples for the exploratory studies