ECUSTEC Baseline Form

FORM TO BE COMPLETED FROM THE CASE NOTES AFTER RANDOMISATION AND BEFORE THE ALLOCATED TREATMENT IS ADMINISTERED

Trial number: ☐☐☐☐☐ Site Name: _____ Date of Birth: __ __ __ / __ __ __ __ (mon/yyyy)

Part A: Recent Medical History

Date of working diagnosis of HUS: (dd/mon/yyyy)	Time of working diagnosis: h h : m m 24 hour clock
Date of arrival at the renal unit: (dd/mon/yyyy)	Time of arrival: h h : m m 24 hour clock
Date seen by paediatric nephrologist: (dd/mon/yyyy)	Time Seen: h h : m m 24 hour clock

Eligible on arrival at the renal unit? ☐ Yes ☐ No*

*If no, state date and time eligibility confirmed: (dd/mon/yyyy) h h : m m 24 hour clock

Clinical Symptom for STEC HUS diagnosis (within last 14 days)	**Date of onset**
Diarrhoea: ☐ Yes * ☐ No	(dd/mon/yyyy)
*If yes, bloody diarrhoea?: ☐ Yes ☐ No	

STEC positive: ☐ Yes* ☐ No ☐ Unknown Household contact STEC positive: ☐ Yes ☐ No

***If STEC positive, results assessed by**: ☐ PCR ☐ Stool ☐ Serology

Serotype if known: _____

Central Nervous System

Any Central Nervous System symptoms in the 48 hours prior to randomisation? ☐ Yes* ☐ No

*If yes, tick all that apply:

Altered consciousness (Agitation, irritability, hallucinations, confusion, excessive drowsiness)	☐ Yes ☐ No
Single seizure	☐ Yes ☐ No
Two or more seizures 24 hours apart	☐ Yes ☐ No

Clinical Data

Blood pressure (average of 3 recordings): ☐☐☐ / ☐☐☐ mmHg

Did the child receive RRT? ☐ Yes ☐ No*

*If no, was the estimated urine output <0.5ml/kg/hr for longer than 12 hours? ☐ Yes ☐ No ☐ Not Known

Part B: Signs and Symptoms for Meningococcal Disease and Septicaemia

Are parents/patient/guardian in possession of the ECUSTEC Meningitis Warning Card and ECUSTEC Patient Study Card? ☐ Yes ☐ No

Part C: Protocol-mandated Therapy (prior to randomisation)

Has trial-mandated antibiotic cover commenced? (penicillin, erythromycin)	☐ Yes* ☐ No
If yes, which trial-mandated antibiotic has been commenced? ☐ Penicillin ☐ Erythromycin ☐ Other	
*If other specify _____	Dose ☐☐☐ mg Frequency _____

Trial Number: ☐☐☐☐☐ Date of Birth: __ __ __ / __ __ __ __ (mon/yyyy)

Part D: Vaccination Status	Yes*	No	*If yes, Date if known
Has the patient received conjugate meningococcal ACWY vaccine (Nimenrix or Menveo)?	☐	☐	(dd/mon/yyyy)
Has the patient received Meningococcal B vaccine (Bexsero™) as part of the **ECUSTEC trial**?	☐	☐	(dd/mon/yyyy)
Has the patient received Meningococcal B vaccine (Bexsero™) as part of the **UK immunisation programme**?	☐	☐	(dd/mon/yyyy)
Unsure if immunised as part of the UK immunisation programme	☐	☐	

Part E:Medical Therapy (7 days prior to randomisation date)

Paracetamol? ☐ Yes ☐ No	Ibuprofen? ☐ Yes ☐ No	
Codeine? ☐ Yes ☐ No	Loperamide? ☐ Yes ☐ No	Other anti-motility agent? ☐ Yes* ☐ No *If yes, please specify _____

Were any other antibiotics given? ☐ Yes ☐ No	Specify antibiotic given:
Start Date: (dd/mon/yyyy)	Stop Date: (dd/mon/yyyy)

Part F(a) : Bloods and Biochemistry To be completed from the case notes. Please state the readings for the parameters below, **for the closest set of values prior to IMP administration.**

Parameter	Reading	Within Local Normal Range Yes	No	Not Done
Neutrophils	☐☐.☐ 10^9/L	☐	☐	☐
White blood cell count	☐☐.☐ 10^9/L	☐	☐	☐
C-reactive protein	☐☐☐.☐ mg/L	☐	☐	☐
Lactate Dehydrogenase (LDH)	☐☐☐☐ U/L	☐	☐	☐
Creatinine	☐☐☐ umol/L	☐	☐	☐
Glucose	☐☐.☐ mmol/L	☐	☐	☐
Amylase	☐☐☐☐ U/L	☐	☐	☐
Alanine transaminase	☐☐☐☐ U/L	☐	☐	☐
Urea	☐☐.☐ mmol/L	☐	☐	☐
Sodium	☐☐☐ mmol/L	☐	☐	☐
Plasma C3 concentration	☐.☐☐ g/L	☐	☐	☐
Plasma C4 Concentration	☐.☐☐ g/L	☐	☐	☐

Part F(b) : Bloods and Biochemistry, Regular Platelet Readings
To be completed from the case notes. Please state the reading **for the closest value prior to IMP administration**

Day	**Recorded? Yes**	**No**	**Date of Reading**	**Platelet Count**	**Had the patient had a platelet transfusion on day of reading? Yes**	**No**
1	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐

Trial Number: ☐☐☐☐☐ Date of Birth: __ __ __ / __ __ __ __ (mon/yyyy)

Part G: Quality of Life Questionnaires (refer to Appendix 3 for age suitable version)

Have the standardised, parent/patient completed, questionnaires been completed at Baseline?

Form	CHU-9D	Peds-QL
Baseline	☐ Yes ☐ No	☐ Yes ☐ No

Part H: Samples (Please indicate which baseline samples have been collected and complete the samples log in the site file)

Optional/Not Optional	Sample Type	Consent given for optional samples?	Was the sample taken?	Notes/problem with sample preparation, if any:
Not optional	Blood EDTA— genetics		☐ Yes ☐ No	
Optional	Blood (EDTA)	☐ Yes ☐ No	☐ Yes ☐ No	
Optional	Blood (co-culture)	☐ Yes ☐ No	☐ Yes ☐ No	
Optional	Urine	☐ Yes ☐ No	☐ Yes ☐ No	

In addition to the trial mandated samples referred to above, please r**emember to forward stool and serum samples to the PHE/SERL laboratories (as appropriate) in accordance with routine practice.**

Part I: Form Completion

Completed by (name): _____

Signed: _____ Date Completed: (dd/mon/yyyy)

PI Name: _____

PI Confirmation Signature: _____ Date Completed: (dd/mon/yyyy)