TO BE PRINTED ON LOCAL TRUST HEADED PAPER

ECUSTEC Trial No.:
☐☐☐☐☐

Participant 16-18yrs Consent Form

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

CONFIDENTIAL ONCE COMPLETED

		Please initial box to confirm consent
1.	I confirm that I have read and understood the information sheet for the ECUSTEC trial (Version Number: ……..). I have had the opportunity to consider the information, ask questions, and these have been answered satisfactorily.	
2.	I understand that my participation in this trial is voluntary and that if I take part I am free to withdraw at any time without giving a reason, and without my medical care or legal rights being affected. I understand that data collected up to my time of withdrawal may be used.	
3.	I understand that information about my progress will be supplied in confidence to the trial coordinators at the Birmingham Clinical Trials Unit (BCTU) by my own doctors for use in the ECUSTEC trial.	
4.	I understand that relevant sections of any of my medical notes may be looked at in confidence by the ECUSTEC research team, responsible individuals from the BCTU, representatives of the sponsor, or from regulatory authorities or from the NHS trust, where it is relevant to my taking part in this research and to check that the trial is being carried out correctly. I give permission for these individuals to have direct access to my records.	
5.	I agree that my GP will be informed of my participation in the ECUSTEC trial.	
6.	Data collected that identifies me by name, consent form, will be transferred from where it is collected and stored at BCTU at the University of Birmingham. I agree to the transfer and storage of this data	
7.	I agree that I may be contacted by the research team in the future regarding further research that is linked to this trial.	
8.	I understand that eculizumab treatment may reduce my natural resistance to infections, especially against 'meningococcus', an organism that causes meningitis (infection of the linings of the brain) and septicaemia (blood infection).	
9.	I agree that I will receive vaccination and preventative antibiotics to reduce the risk of meningococcal infection	
10.	I agree that a certificate confirming that vaccination has taken place and that preventative antibiotics are being given to me will be sent to the manufacturers of eculizumab (Alexion Pharmaceuticals). If a serious unexpected event or pregnancy occurs within 6 months of enrolment, the trial team may need to notify Alexion Pharmaceuticals. In all communication with Alexion Pharmaceuticals I will only be identified by my unique trial number.	
11.	I agree that a sample of blood (containing my DNA) can be sent to Bristol University to be stored for analysis of the genes associated with HUS at an approved laboratory to help interpret the results of the trial	

12. I agree that a blood sample can be taken at 12 months and will be sent for analysis at East Kent Hospitals University NHS Foundation to look at my kidney function. ☐
13. I agree that a stool sample can be collected and sent to Public Health England Microbiological Reference Laboratory to be analysed for STEC. I understand that a positive result from this testing will be fed back to ensure public health follow up can be arranged. ☐
14. I agree to take part in the ECUSTEC trial. ☐

In order to participate in the ECUSTEC trial, consent to parts 1-14, above, is required.

Points 15-18, below, are optional. You should only initial points 15-18 if you agree to them.

15. I agree that optional research blood and urine samples can be taken from me, stored and used for research to look for further evidence of what causes STEC HUS. ☐
16. I agree to the DNA sample used to test the genes associated with HUS undergoing further optional detailed analysis of all potentially relevant genes (whole exome sequencing). I understand that results from this testing will not be fed back unless it is directly relevant to my illness. ☐
17. I agree that an additional, optional, one-off 10ml blood sample may be taken from me to see how my white blood cells interact with kidney cells in the laboratory. ☐
18. I agree to my blood and urine samples being taken, extracted DNA being stored and used for research both within this study and in future related studies. Any such studies on these samples would require Research Ethics Committee approval. ☐

Name of Participant	Date (dd/mmm/yyyy)	Signature

Name of Researcher	Date (dd/mmm/yyyy)	Signature

If an interpreter has translated this form they should countersign here to certify that they have translated fully and accurately

Name of Translator	Date (dd/mmm/yyyy)	Signature

Original to be kept in the ECUSTEC site file, one copy for the participant, one copy kept with patient's notes and one copy sent to BCTU.