TO BE PRINTED ON LOCAL TRUST HEADED PAPER

**DAY 30 INFORMATION REGARDING FOLLOW-UP MENINGOCOCCAL VACCINATION**

**Study Title**

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

This guidance applies to children ***over the age of 2 years*** at enrolment to the ECUSTEC study and **not** already receiving Bexsero as part of UK Vaccination Schedule

Dear Parent

**Thank you for allowing your child to take part in the ECUSTEC study.**

Your child received two doses of trial medicine (eculizumab or inactive medicine). As you may recall, we have also given your child protection against meningococcal infection because the study drug (eculizumab) increases the risk of developing meningococcal infection. The protection was as follows:

1. Meningococcal vaccination (including one dose of the meningitis B vaccine Bexsero)
2. Penicillin medicine twice daily for 8 weeks

We also gave you information about the signs and symptoms of meningococcal disease.

Because the study medicine will not continue in the long-term, the risk of meningococcal infection will reduce down to the same as the normal population by the time your child comes for their next study visit (day 60). You should continue giving them penicillin medicine until day 56. After that time your child will not need additional protection from meningococcal infection.

Because your child has not received a full course of meningococcal vaccination, any effect of the vaccine is not likely to be long lasting. **However, we would like to offer your child the full course of the meningitis B vaccine (Bexsero), of which they have received the first dose.** This is entirely optional, and not required for continuation in the trial.

The full course of Bexsero for your child would require

1. First vaccine - already given
2. Second vaccine 2 months later (we can give this at the next study visit)

If you have any questions about this, please ask your doctor, research nurse or GP. Please let your doctor or research nurse know whether you would like to take up this offer and they will arrange for the next dose to be given at your next visit and notify your child’s GP.

Please be aware that no vaccination can protect against all the possible causes of meningitis and septicaemia and that if you are worried about your child in the future you should seek medical advice.

Once again, many thanks for your child’s participation in the ECUSTEC study

Yours faithfully

<Insert Local PI Name>,

<Insert Local PI Tel. No.>

ECUSTEC Principal Local Investigator

For queries about the trial 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 trial co-ordinating centre is located at the Birmingham Clinical Trials Unit, College of Medical & Dental Sciences, Institute of Applied Health Research, University of Birmingham, Edgbaston, Birmingham B15 2TT. Tel 0121 415 9132, Fax: 0121 415 9135, Web address: www.birmingham.ac.uk/ECUSTEC.

**Thank you for your child’s participation in this trial**