

## User Guide to the UK Meningitis Protocol

### 1. Screening

- Screening Criteria
  - Suspected Meningitis
  - Aged over 16

**Screening number** = site number followed by sequential numbers commencing at 01. E.g. if you are site number 25 your screening numbers would start at 2501, 2502, 2503 etc...

Please record all people screened on the **screening log**.

### 2. Enrolment

- Inclusion/eligibility criteria
  - Suspected meningitis
  - Aged over 16
  - Have had/going to have an LP

If a pt is deemed to be eligible please give them a patient information sheet. If the patient is then agreeable they should sign the consent form and fill in the participant details form. ***(please note the consent form, the participant detail form and the enrolment form should all have the screening number on them)***

Please fill in the **enrolment log**.

Fax the **consent form, participant details form and enrolment form** to the UOL (0151 795 5528). If you do not have a fax please phone on 0151 795 9606 to enrol the patient. Once a fax or phone call is received with the enrolment form and screening number a **subject ID** will be generated from the database and given to you. Once you have the subject ID you can continue with data collection.

A confirmation of enrolment form will be sent to site with the screening number and the subject ID on it.

### 3. Data collection/study procedures.

Please fill in the **CRF** leaving no blanks (if appropriate record **NR, NK or NA**). The **Subject ID** should be inserted on **ALL** pages of the CRF.

If you are taking part in the substudies and the pt has consented please take the extra samples (blood +/- CSF) following the sampling procedure in the site file, fill in the **sample log** and send to the laboratory using the stickers provided.

Before the patient goes home please give them a copy of the **Total Morbidity Score (TMS)** and a pre paid envelope. Fill in the subject ID on **ALL** pages before giving to the patient. Please assist the patient by filling in the date of admission for day 1 and continuing. Please explain to them what they need to do and give them a thermometer to take home with them. When they have completed the TMS they should put it in the envelope provided and return to me. They can keep the thermometer!

#### **4. Discharged Patients**

If a patient is discharged before you become aware of them please send them the prewritten letter in the ISF with a patient information sheet, consent form and pre paid envelope. They will then return the consent form to me. If I receive a consent form I will fax a copy to site with a confirmation of enrolment form and data collection can begin at site. **Please ensure the screening number is on the consent form before it is sent to the patient.**

#### **5. Adverse Events**

Adverse events can be recorded on the forms provided. Adverse events would be such things as hospital acquired infection, post LP headache etc...

#### **6. Filing**

Original Consent forms and CRFs should be kept in the ISF – or an extension of the ISF.

#### **7. Supplies**

Please contact me by e-mail or phone if you need more envelopes/thermometers/blood tubes.