

SepTiC Eligibility form

Complete this form as part of the screening process for the SepTiC trial – **to be completed by a clinician (listed on the delegation log)** and filed in the medical records once complete.

Inclusion Criteria	Please circle which apply	
Adults (≥ 16 years of age) admitted to ICU due to suspected sepsis and expected to stay for at least two calendar days (i.e. expected to still to be in ICU the day after tomorrow)	Yes	No
Receiving intravenous antibiotics for suspected sepsis	Yes	No
According to local clinical judgement, patient has received adequate initial early fluid resuscitation	Yes	No

Exclusion Criteria	Please circle which apply	
More than 24 hours since ICU admission (<u>this does NOT apply for intervention 3, GM-CSF</u>).	Yes	No
Previously admitted to ICU due to sepsis on this hospital admission	Yes	No
Not expected to survive 90 days, due to pre-existing chronic (end-stage) disease	Yes	No
Not expected to survive initial resuscitation (24 hours)	Yes	No
Neutropaenia (< 0.5 neutrophils $\times 10^9$ /L) due to chemotherapy/malignancy (but not due to sepsis)	Yes	No
A source of infection that will require a prolonged course of antibiotics, for greater than 21 days (e.g., infective endocarditis, osteomyelitis, hepatic or cerebral abscess, tuberculosis)	Yes	No
Diabetic ketoacidosis (DKA) or hyperglycaemic hyperosmolar state (HHS)	Yes	No
Within 21 days of a spontaneous subarachnoid haemorrhage	Yes	No
Diabetes Insipidus	Yes	No
Weight < 40 Kg	Yes	No

Is the subject eligible to participate in the fluid and diagnostic arms of the study? **YES / NO**

I confirm that patient (name) _____

has been screened for the SepTiC study and is suitable to be enrolled.

Form completed by: (name of clinician) _____

(signature) _____ on ____/____/____ (date)

To complete eligibility for the GM-CSF please complete page 2 of this form.

SepTiC – Additional eligibility for GM-CSF only

Complete this form as part of the screening process for the GM-CSF trial only (can be done only after initial entry)

Inclusion Criteria	Please circle which apply	
Intubated and mechanically ventilated and expected to continue for another 24 hours <u>or</u> requiring two organ support (i.e. vasopressors or renal replacement therapy)	Yes	No
An absolute lymphocyte count < 1.2 x10 ⁹ /L on two consecutive calendar days at least 12 hours apart, with no values >1.2 x10 ⁹ /L in between.	Yes	No

Exclusion Criteria	Please circle which apply	
More than 120 hours (5 days) since ICU admission	Yes	No
Already receiving G-CSF or GM-CSF	Yes	No
A total white blood cell count (WBC) >50 x10 ⁹ /L	Yes	No
Allergy, anaphylaxis or previous adverse reaction to GM-CSF or yeast-derived products	Yes	No
Known to be pregnant or breastfeeding	Yes	No
Known recent (required treatment within the last 5 years) haematological malignancy	Yes	No
Solid organ or bone marrow transplantation	Yes	No
Patient weight >125kg	Yes	No

Is the subject eligible to participate in the GM-CSF arm of the study? YES / NO

I confirm that patient (name) _____

has been screened for the SepTiC study and is suitable to be enrolled.

Form completed by: (name of clinician) _____

(signature) _____ on ____/____/____ (date)