Form number: 2

Randomisation Form

sepsis adapt
Biomarker-guided antibiotic duration for sepsis

Randomising Site:

A: PATIENT DETAILS—to be completed at Time 0

1) Participant Initials: ☐☐

2) Gender: Male ☐ Female ☐

3) Date of birth: d d – m o n – y y y y

4) NHS/CHI Number: ☐☐☐☐☐☐☐☐☐☐

B: CONSENT (Part 1).

1) Type of consent (check one only):

Patient ☐ Trust Nominated Consultee ☐

Personal Consultee/Next of Kin/Guardian/Welfare Attorney ☐

2) Date consent obtained: d d – m o n – y y y y 3) Version of consent form ☐•☐

(Please note: your name must be on the trial delegation log)

4) Person taking consent: _____

B: Consent (Part 2) **RISC-Sepsis participating sites only**

1) Is your site taking part in the RISC-Sepsis sub study? No ☐ Yes ☐

2) Consent form optional statement 9 initialled (additional blood sampling & storage for RISC-Sepsis) No ☐ Yes ☐

C: ELIGIBILITY

1) Does the patient fulfil all the eligibility criteria? No ■ Yes ☐

2) Has a clinician confirmed eligibility? No ■ Yes ☐

3) Date eligibility confirmed: d d – m o n – y y y y

D: STRATIFICATION FACTORS

1) Severity: Does the patient have suspected Septic Shock? No ☐ Yes ☐

2) Has the patient had surgery within last 72 hours: No ☐ Yes ☐

E: RANDOMISATION DETAILS *(To be completed when patient has been randomised and allocated a trial number)*

1) Participant trial number: ☐☐☐☐

2) Date and time of randomisation: d d – m o n – y y y y h h : m m

Form completed by (print name): _____

(Please note: your name must be on the trial delegation log)

Signature: _____ **Date signed:** d d – m o n – y y y y

Completion Guidelines for CRF 2: Randomisation Form

Prior to randomisation, the Eligibility Form should be completed. A patient should only be randomised if they meet the eligibility criteria.

Participant Initials:	Write the initials of the participant's first/given name and surname/family name only. For double barrelled surnames/ family names use the initial from the first part of the surname/family name.
Dates:	Please use the following formats for all dates: 06-Jun-1956.
Times:	Please record all times in the 24-hour format.

- Date and version of consent form will be included in the footer of the document. Please enter this as it is recorded.
- The trial number will be allocated once the patient has been randomised. If completing a paper randomisation form, please enter the trial number after randomisation.
- In the event of system failure **only,** complete an emergency randomisation by dialling 02476 150402.

Types of consent

Personal Consultee/Next of Kin - A friend or relative who has considered the wishes of the patient and if they would have any objections to taking part in this research, if they were well enough to think about this information for themselves.

Trust Nominated Consultee - A professional who has been provided with information about this research and has agreed to be contacted to consider the participation of a patient, when a Personal Consultee cannot yet be identified, or has declined to undertake this role. This individual will be independent to and have no other involvement in this study. *Please note – this does not apply to Scotland or Northern Ireland*.

Guardian or Welfare Attorney - An individual nominated by the patient who will consider the patient's wishes and if they would have any objection to taking part in this research, if they were well enough to think about this information for themselves. *Please note - this applies to Scotland only.*

Definition of surgery

A surgical procedure conducted in a hospital operating theatre whether under general, regional or local anaesthetic.

Definition of Suspected Sepsis and Suspected Septic Shock

Mervyn Singer et al. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3).

	Sepsis	Septic Shock
2015 Definition:	Sepsis is a life-threatening organ dysfunction caused by dysregulated host response to infection	Septic shock is a subset of sepsis in which underlying circulatory and cellular/metabolic abnormalities are profound enough to substantially increase mortality
2015 Clinical criteria:		Sepsis and vasopressor therapy needed to elevate MAP ≥65mm Hg and lactate >2 mmol/L (18 mg/dL) despite adequate fluid resuscitation