EVIS: Information Sheet for Clinical Staff: CONTROL Arm

Study: **EVIS:** Early Vasopressors in Sepsis (**EudraCT No:** 2021-006886-39)

EVIS Participant No.:		Insert Patient ID/Addressograph label
Randomisation: This patient has been randomised to the **USUAL/STANDARD CARE arm** of the EVIS study.		

Participant randomised on:
_____ *(insert date)* **at** _____ *(insert time hh:mm)*

If you need more information:

- Contact the Research Team on _____
- The protocol and other current study documents can be found on the website www.evis.scot.nhs.uk or by scanning the QRS code opposite

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Key information for CLINICIANS for STANDARD CARE (CONTROL) arm

Randomisation: Standard Care (Control) arm

Study treatment period: maximum 48 hours from time of randomisation. See above.

IMPORTANT: Only trained research staff on the site delegation log can initiate study treatment with permitted balanced crystalloid IV fluids. Thereafter, treating clinicians should continue study treatment with balanced crystalloid IV fluids as below.

Initial treatment (3 hours post-randomisation)

- Fluid resuscitation: Administer balanced crystalloid intravenous fluid via PERIPHERAL venous cannula.
- Titrate intravenous fluid administration to target MAP ≥ 65 mmHg.
- Permitted balanced crystalloid IV fluids (any brand)
  - Compound Sodium Lactate Solution for Infusion (Ringers Lactate or Hartmanns solution)
  - Plasma-Lyte 148 Solution for Infusion

Anticipated most participants will receive up to approximately 30ml/kg in the first 3 hours using 250-1000ml rapid infusion (bolus) of the permitted balanced crystalloids for fluid resuscitation.

Ongoing treatment (up to 45 hours post-randomisation)

- Further balanced crystalloid boluses for resuscitation is at discretion of clinical team.
- Titrate intravenous fluid administration to target MAP ≥ 65 mmHg.

Maintenance and rescue treatment that may be prescribed by the treating clinician

- **Rescue vasopressors:** Rescue vasopressor of clinician choice via CENTRAL line. Participants must not receive any peripheral vasopressor infusion during the 48 hour study period even where peripheral administration is accepted practice at site.
- **Maintenance intravenous fluids:** Defined as any fluid at a rate of ≤125ml/hour
- **Requirement for operative intervention:** Maintain treatment allocation where possible. Anaesthetist discretion permitted for other fluids, blood product and vasopressor use.
- **End of study period** *(> 48 hours since randomisation)*: Treatment may continue as per standard care once the EVIS study period is completed.

Other treatment: As per UK national guidelines/local protocols on sepsis.