**Site Capability Assessment**

A new study in the early use of vasopressors in sepsis is in set up and you have been sent this questionnaire as you have previously expressed interest in becoming a participating site. The Chief Investigator for the study **Professor Alasdair Corfield** would like to invite you to participate. The purpose of this questionnaire is to confirm your interest and to help us assess the feasibility of conducting this study at your site. Please complete this as accurately as possible and email to **Hannah Greenwood** at **Hannah.Greenwood@nhs.scot** at your earliest convenience.

We strongly encourage a collaborative approach between Emergency Medicine and Critical Care for delivery of this study. If you have any questions about the trial or completing this questionnaire, please contact the Chief Investigator: Dr Alasdair Corfield – alasdair.corfield2@nhs.scot or Project Manager: Hannah Greenwood – Hannah.Greenwood@nhs.scot

|  |  |
| --- | --- |
| **Study Title:**  | **Early Vasopressors in Sepsis** |
| **Chief Investigator:** | **Prof Alasdair Corfield** |
| **Sponsor:** | **NHS Greater Glasgow & Clyde** |
| **Planned start date of trial:** | **August 2022** |
|  |  |
| **Site Name:** |  |
| **Full postal Address:** |  |
| **Principal Investigator:** |  |
| **Telephone No:** |  |
| **Email address:** |  |

|  |
| --- |
| **Local Key Contact Details****(e.g. co-investigators, research fellows, Research Nurses, etc)****Emergency Medicine Lead:** |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |
| **Critical Care Lead:** |  |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |
| **Lead Research Nurse:** |  |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |

|  |
| --- |
| **Local Pharmacy Contact Details**  |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |

|  |
| --- |
| **Local R&I Contact Details** |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |
|  |  |
| **Name:** |  |
| **Designation:** |  |
| **Tel:** |  |
| **Email:** |  |

|  |  |
| --- | --- |
| **Are you interested in participating in this trial?** | **Yes / No** (*please delete as appropriate*) If No, ­­please briefly provide your reason:If you have answered ‘No’, please move straight to the signature section at the end of the form and return as detailed above. |
| **Would you be able to support the associate PI scheme for a suitable trainee?**  | **Yes / No** *(please delete as appropriate)*(<https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040>)  |
|   |
|  |
| **Recruitment and Capacity*****It is anticipated that each site will be responsible for recruiting an average of 1 participant per month.***  |
| Do you feel your site will be able to recruit to target as detailed in the statement above?  | **Yes / No** (*please delete as appropriate)* |
|  |
| How many potentially eligible patients does your site see per year? *Please see Clinical Trial Synopsis/Protocol (if available) for eligibility criteria.* | (Please state) |
|  |
| What methods will you use to recruit participants? (*e.g. patient database, electronic medical records, referral etc.)* | (Please state) |
|  |
| Do you have any current or potential new trials which may compete against or affect recruitment to this trial? | **Yes / No** (*please delete as appropriate)* |
|  |
| Are you aware of any national or local guidelines that will impact on the recruitment of this trial? | **Yes / No** (*please delete as appropriate)* |
|  |
| Do you have the staff capacity to undertake this trial (e.g. research nurses, data managers, etc.)? | **Yes / No** (*please delete as appropriate)* |
| **Clinical Trial Experience** |
| Have you been a Principal Investigator (PI) before? | **Yes / No** (*please delete as appropriate)* |
|  |
| Number of trials you have worked on as a PI in the last 12 months? | (Please state) |
|  |
| How many of these trials were in this therapeutic area? | (Please state) |
|  |
| Have you worked on a trial with **NHS Greater Glasgow & Clyde** in the last 12 months? | **Yes / No** (*please delete as appropriate)* |
|  |
| Are you trained in Good Clinical Practice (GCP)? | **Yes / No** (*please delete as appropriate)**Date of training:* |
|  |
| Are all site staff who will be participating in the trial at your site, including the pharmacist (if applicable), GCP trained? | **Yes / No** (*please delete as appropriate)* |

|  |
| --- |
| **Protocol Specific Assessments** |
| Does the trial protocol match your standard pathway for this group of patients?  |  **Yes / No** (*please delete as appropriate)**If no, please comment:* |
|  |
| Can your site comply with the protocol schedule? Please comment on any areas of concern you have.  | **Yes / No** (*please delete as appropriate)* |
|  |
| Will you be able to comply with the follow-up schedule? | **Yes / No** (*please delete as appropriate)* |
|  |
| Will any trial procedures or study follow-up be performed out with your site?  | **Yes / No** (*please delete as appropriate)**If yes, please comment:* |

|  |
| --- |
| **Inclusion/Exclusion Criteria****Would any of the following inclusion/exclusion criteria represent any substantial difficulty for recruiting subjects into this study?** |
|  |
| **Inclusion Criteria** | **Causes difficulties with recruitment?** | **If Yes, please comment:** |
| Adults (18 years and older) meeting all of the 3 criteria below: | Yes/No |  |
| Clinically suspected or proven infection resulting in principal reason for acute illness | Yes/No |  |
| SBP < 90 mmHg or MAP of < 65 mmHg (within an hour of eligibility assessment) or measured serum lactate of > 2mmol/L at the time of eligibility assessment | Yes/No |  |
| Hospital presentation within last 12 hours | Yes/No |  |
| **Exclusion Criteria** | **Causes difficulties with recruitment?** | **If Yes, please comment:** |
| > 1500ml of intravenous fluid prior to screening | Yes/No |  |
| Requirement for immediate surgery | Yes/No |  |
| Immediate requirement for central venous access | Yes/No |  |
| Chronic renal replacement therapy | Yes/No |  |
| Known allergy/adverse reaction to norepinephrine | Yes/No |  |
| Palliation/end of life care | Yes/No |  |
| Previous recruitment in the trial | Yes/No |  |
| Patients with permanent incapacity | Yes/No |  |
| Pregnancy | Yes/No |  |
| Other primary causes of shock | Yes/No |  |
| History or evidence of any other medical, neurological or psychological condition that would expose the subject to an undue risk of a significant Adverse Effect as determined by the clinical judgement of the investigator | Yes/No |  |
| Participation in other clinical trials of investigational medicinal products | Yes/No |  |

|  |
| --- |
| **General Site Information** |
| What is the anticipated set-up time for this trial at your site?  |   |
|  |
| Are there any local groups or committees the trial must be submitted to for approval?  |  |
|  |
| The Sponsor may perform pre-arranged site visits for monitoring and audit purposes. Are you able to provide the necessary staff support and access to selected patient notes and trial documents for these site visits? | **Yes / No** (*please delete as appropriate)* |
|  |
| The eCRF will be compatible with all HTML5 browsers such as Chrome, Microsoft Edge, Safari, Firefox and Opera.Do you foresee any difficulty in accessing the eCRF? | **Yes / No** *(please delete as appropriate)* |

**Thank you for taking the time to complete this form.**

|  |  |
| --- | --- |
| **Completed by:** |  |
| **Designation:** |  |
| **Date:** |  |

|  |
| --- |
| **\*\*\*Please forward this completed form by email to the Study Project Manager\*\*\*** |
| **Hannah Greenwood –** **Hannah.Greenwood@nhs.scot** |