If checked select **one** option only:

**SPIRAL DATABASE FORM V10.0**

Your site’s database account will be setup in accordance with this document. Update and re-submit this form if anything changes. This form should be completed in accordance with relevant Research Governance Office and Human Research Ethics Committee approvals.

# Section 1: Site Details

|  |  |  |
| --- | --- | --- |
| **Site Details** |  |  |
| Hospital Name: | Click here to enter text. | |
| Site Identifier (provided by sponsor) | Click here to enter text. | |
| Country: | Click here to enter text. | |
| ICU Chart day start time:  *The time a new day starts on your ICU chart* | Click here to enter text. hrs (24-hour clock) | |
| Time-zone | Click here to enter text. | |
| **Primary contact at your site** (used on study tools provided centrally) | | |
| Name: | Click here to enter text. | |
| Email address: | Click here to enter text. | |
| Phone number: | Click here to enter text. | |

|  |  |  |
| --- | --- | --- |
|  |  | |
| **Units of measurement**  Check the unit of measurement used at your site. If you use more than one, check both boxes | | |
| Height | cm | feet and inches |
| Weight | kg | lbs |
| Creatinine | μmol/L | mg/dL |
| Bilirubin | μmol/L | mg/dL |
| Pressure | mmHg | kPa |
| Troponin | ng/L | ng/mL |
| Platelet count | cells x 109/L | cells/mm3 |
| Temperature | Centigrade | Fahrenheit |

|  |  |  |  |
| --- | --- | --- | --- |
| **D-dimer test details** | | | |
| D-dimer upper limit of normal  (for adults aged < 50 years) at your site | \_\_\_\_\_\_\_\_\_\_\_\_\_ | | μg/L or ng/mL |
| μg/mL or mg/L |
| Is d-dimer reported as FEU or DDU at your site? |  | Fibrinogen Equivalent Units (FEU) | |
|  | D-Dimer Units (DDU) | |
| Which d-dimer laboratory analytic system is used at your site? |  | IL Hemosil | |
|  | Siemens Innovance | |
|  | Stago Liastest | |
|  | Other | |

# Section 2: Domain Participation

Check the domains you will participate in

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Domain** | **Non-Pandemic** | **Pandemic** | | |
| **ICU Organ Support** | **ICU Organ Support** | **ICU No Organ Support** | **Ward** |
| Antibiotic Domain |  |  |  |  |
| Macrolide Duration |  |  |  |  |
| Corticosteroid Domain |  |  |  |  |
| Influenza Antiviral Domain |  |  |  |  |
| Vitamin C Domain |  |  |  |  |
| Statin Therapy Domain |  |  |  |  |
| Mechanical Ventilation Domain |  |  |  |  |
| ACE2 RAS Domain |  |  |  |  |
| Anticoagulation Domain |  |  |  |  |
| COVID-19 Antiviral Domain |  |  |  |  |
| Cysteamine Domain |  |  |  |  |

Section 3: Antibiotic Domain Intervention Participation

Check the antibiotic domain interventions you will participate in

|  |  |  |
| --- | --- | --- |
| **Antibiotic Intervention** | **Non-pandemic** | **Pandemic** |
| **ICU Organ Support** | |
| Ceftriaxone |  |  |
| Piperacillin-tazobactam |  |  |
| Ceftaroline |  |  |
| Amoxicillin-clavulanate |  |  |
| Moxifloxacin OR Levofloxacin  If checked select **one** option only: |  |  |
|  |  |  |
| Moxifloxacin | |  |
| Levofloxacin | |  |

|  |  |
| --- | --- |
| Delayed consent permitted | Prospective consent required |

Section 4: Macrolide Duration Domain Intervention Participation

Rank your sites choice of IV and enteral macrolide for use in the macrolide duration domain.

*Rank from 1-5 (1 = first preference). If a preparation is not available or not appropriate leave blank. Initial IV administration is strongly preferred and the preferred IV macrolide is azithromycin. The information provided here will be used on the database randomisation page to guide users on which macrolide to prescribe.*

|  |  |  |
| --- | --- | --- |
| **Macrolide Antibiotic Options** | **Non-pandemic** | **Pandemic** |
|  | **ICU Organ Support** | |
| **IV Preparation** | (1= first choice) | |
| IV Azithromycin (management committee preferred) |  |  |
| IV Clarithromycin |  |  |
| Enteral Azithromycin |  |  |
| Enteral Clarithromycin |  |  |
| Enteral Roxithromycin |  |  |

|  |  |
| --- | --- |
| Delayed consent permitted | Prospective consent required |

Section 5: Corticosteroid Domain Intervention Participation

Check the corticosteroid domain interventions you will participate in.

|  |  |
| --- | --- |
| **Corticosteroid Intervention** | **Non-pandemic** |
| **ICU Organ Support** |
| No corticosteroid (no placebo) |  |
| Fixed-duration Hydrocortisone  (50mg IV 6-hourly for 7 days) |  |
| Shock-Dependent Hydrocortisone  (50mg IV 6-hourly during septic shock) |  |

|  |  |
| --- | --- |
| Delayed consent permitted | Prospective consent required |

Section 6: Influenza Antiviral Domain Intervention Participation

Check the Influenza Antiviral domain interventions you will participate in. Please note that all sites participating in the Influenza Antiviral Domain must participate in the five-day Oseltamivir intervention.

|  |  |  |
| --- | --- | --- |
| **Influenza Antiviral Intervention** | **Non-pandemic** | **Pandemic** |
| **ICU Organ Support** | |
| No antiviral agent (no placebo) |  |  |
| Oseltamivir for 5 days |  |  |
| Oseltamivir for 10 days |  |  |

|  |  |
| --- | --- |
| Delayed consent permitted | Prospective consent required |

Section 7: Vitamin C Domain Intervention Participation

Check the Vitamin C Domain interventions you will participate in.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Vitamin C Intervention** | **Non-Pandemic** | **Pandemic** | | |
| **ICU Organ Support** | | **ICU No Organ Support** | **Ward** |
| No Vitamin C |  |  |  |  |
| Vitamin C |  |  |  |  |

|  |  |
| --- | --- |
| Delayed consent permitted | Prospective consent required |

Section 8: Simvastatin Domain Intervention Participation

Check the Simvastatin Domain interventions you will participate in.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Simvastatin Intervention** | | **Pandemic** | | |
| **ICU Organ Support** | **ICU No Organ Support** | **Ward** |
| No Simvastatin |  | |  |  |
| Simvastatin |  | |  |  |

|  |  |
| --- | --- |
| Delayed consent permitted | Prospective consent required |

Section 9: Mechanical Ventilation Domain Intervention Participation

Check the Mechanical Ventilation Domain interventions you will participate in.

|  |  |  |  |
| --- | --- | --- | --- |
| **Mechanical Ventilation Intervention** | | **Non-Pandemic** | **Pandemic** |
| **ICU Organ Support** | |
| Clinician-preferred mechanical ventilation strategy | |  |  |
| Protocolised mechanical ventilation strategy | |  |  |
| If checked select **one** option only: | |  |  |
|  | Protocolised strategy | Standard PEEP (ARDSnet protocol)  High PEEP (LOVS / ALVEOLI protocol) | |

|  |  |
| --- | --- |
| Delayed consent permitted | Prospective consent required |

Section 10: COVID-19 Antiplatelet Domain Intervention Participation

Check the Antiplatelet Domain interventions you will participate in.

If checked select **one** option only:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **COVID-19 Antiplatelet Intervention** | | **Pandemic** | | |
| **ICU Organ Support** | **ICU No Organ Support** | **Ward** |
| No antiplatelet |  | |  |  |
| Aspirin |  | |  |  |
| P2Y12 inhibitor |  | |  |  |
|  |  | | |  |
|  | Clopidogrel | | |  |
|  | Prasugrel | | |  |
|  | Ticagrelor | | |  |

|  |  |
| --- | --- |
| Delayed consent permitted | Prospective consent required |

Section 11: ACE2 RAS Domain Intervention Participation

Check the ACE2 Renin-Angiotensin System Modulation Domain interventions you will participate in. You must specify your site preferred ACEi and ARB agent for if participating in these interventions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **COVID-19 ACE2 RAS Intervention** | **Pandemic** | | | |
| **ICU Organ Support** | | **ICU No Organ Support** | **Ward** |
| No RAS inhibitor |  | |  |  |
| ACEi  If checked select **one** option only:  Ramipril  Lisinopril  Perindopril  Enalapril  Trandolapril  Captopril |  | |  |  |
|  | | | |  |
| ARB  If checked select **one** option only:  Losartan  Valsartan  Candesartan  Irbesartan  Olmesartan  Telmisartan |  |  | |  |
|  | | | |  |
| ARB + DMX-200  If checked select **one** option only:  Losartan + DMX-200  Valsartan + DMX-200  Candesartan + DMX-200  Irbesartan + DMX-200  Telmisartan + DMX-200  Olmesartan + DMX-200 |  |  | |  |
|  | | | |  |

|  |  |
| --- | --- |
| Delayed consent permitted | Prospective consent required |

Section 12: Anticoagulation Domain Intervention Participation

Check the Anticoagulation Domain interventions you will participate in.

TAC = Therapeutic dose anticoagulation.

|  |  |  |
| --- | --- | --- |
| **Anticoagulation Intervention** | **Pandemic** | |
| ***ICU Organ Support*** | |
| ***No Prior TAC*** | ***Prior TAC*** |
| Conventional low dose thromboprophylaxis |  |  |
| Intermediate dose thromboprophylaxis |  |  |
| Continuation of therapeutic dose anticoagulation |  |  |

|  |  |
| --- | --- |
| Delayed consent permitted | Prospective consent required |

Section 13: COVID-19 Antiviral Intervention Participation

Check the COVID-19 Antiviral Domain interventions you will participate in.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Ivermectin Intervention** | | **Pandemic** | | |
| **ICU Organ Support** | **ICU No Organ Support** | **Ward** |
| No Ivermectin |  | |  |  |
| Ivermectin |  | |  |  |

|  |  |
| --- | --- |
| Delayed consent permitted | Prospective consent required |

Section 14: Cysteamine Domain Intervention Participation

Check the Cysteamine Domain interventions you will participate in.

|  |  |  |
| --- | --- | --- |
| **Cysteamine Intervention** | **Non-pandemic** | **Pandemic** |
| **ICU Organ Support** | |
| No Cysteamine (no placebo) |  |  |
| Cysteamine |  |  |

Section 15: Individual database accounts

Please list all of the people at your site who require an individual account to the database. **Each site must include at least one Research Coordinator and one Investigator.**

|  |  |  |
| --- | --- | --- |
| **Full name**  (shown on database) | **Email address**  (used to set-up database & receive notifications) | **Role** |
|  |  | Choose an item. |
|  |  | Choose an item. |
|  |  | Choose an item. |
|  |  | Choose an item. |
|  |  | Choose an item. |
|  |  | Choose an item. |
|  |  | Choose an item. |
|  |  | Choose an item. |
|  |  | Choose an item. |

|  |  |
| --- | --- |
| **PI Authorisation** | |
| *PI Full Name:* |  |
| *Signature:* |  |
| *Date:* | Click or tap to enter a date. |

**Please send the signed copy of this form to your sponsor**