

## STRESS-L Trial Participant Completion Checklist

No.	Task	Guidance	Done
1	Screen patient	<ul style="list-style-type: none"> <li>ICU patients with septic shock diagnosis as per Sepsis-3 criteria, received vasopressors for 24 hours and noradrenaline should be screened.</li> </ul>	<input type="checkbox"/>
2	Complete eligibility form and document in medical notes	<ul style="list-style-type: none"> <li>Update patient's medical notes to document the patient is eligible for the trial. The documentation of the eligibility must include the current heart rate and noradrenaline dose at the time of the assessment, time of noradrenaline start and time lactate criteria achieved.</li> <li>Paper CRF eligibility form must be signed by appropriately delegated medically qualified physician.</li> </ul>	<input type="checkbox"/>
3	Obtain consent	<ul style="list-style-type: none"> <li>If patient lacks capacity, obtain consent from Personal Legal Representative (PerLR). Research nurse can obtain consent from PerLR if local NHS Trust policy permits.</li> <li>If PerLR not available, obtain consent from Professional Legal Representative (ProLR).</li> </ul>	<input type="checkbox"/>
4	Randomise patient	<ul style="list-style-type: none"> <li>Dial <b>02476 932 036</b> to randomise patient via automated 24/7 IVR system.</li> <li>Complete paper CRF randomisation form. Appropriately delegated member of staff must sign form.</li> </ul>	<input type="checkbox"/>
5	Obtain Day 0 blood samples	<ul style="list-style-type: none"> <li>All blood samples must be taken for <u>both arms</u> (interventional &amp; standard care). <b>Blood samples <u>should not</u> be taken for suspected or confirmed positive COVID-19 patients.</b></li> <li>Interventional arm: take prior to start of Landiolol administration</li> <li>Please refer to lab manual for further guidance.</li> </ul>	<input type="checkbox"/>
6	Complete baseline ECG	<ul style="list-style-type: none"> <li>Complete for <u>both arms</u> (interventional &amp; standard care)</li> <li>Take up to 24 hours prior to randomisation</li> </ul>	<input type="checkbox"/>
7	Commence Landiolol Infusion	<ul style="list-style-type: none"> <li>If randomised to landiolol arm <b>only</b>.</li> <li>Refer to IMP management manual and Landiolol Dosing chart laminates for further guidance.</li> </ul>	<input type="checkbox"/>
8	Baseline data collection	<ul style="list-style-type: none"> <li>Following critical data must be entered within 24 hours post randomisation: <ul style="list-style-type: none"> <li>- &gt; Noradrenaline start date and time</li> <li>- &gt; Other vasopressor start date and time</li> <li>- &gt; Heart Rate Day 0 Hour 0</li> <li>- &gt; Noadrenaline Dose Day 0 Hour 0</li> </ul> </li> </ul>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9	Submit paper CRFs	<ul style="list-style-type: none"> <li>Paper eligibility and randomisation forms must ideally be submitted to WCTU within 24 hours post randomisation.</li> <li>Temporary Inotrope and Beta Blocker Dosage CRFs to be completed and returned on paper at Day 14 until database is updated.</li> <li>Please refer to Data Transfer Working Instructions for further guidance.</li> </ul>	<input type="checkbox"/> <input type="checkbox"/>
10	Daily data collection	<ul style="list-style-type: none"> <li>Completed up until Day 14 as long as the patient remains on ICU.</li> <li>Please refer to CRF instructions for further guidance.</li> </ul>	<input type="checkbox"/>
11	Blood sample collection	<ul style="list-style-type: none"> <li>Day 0: x1 PaxGene RNA, x1 PaxGene DNA, x3 Green Lithium Heparin tubes</li> <li>Day 1: x1 PaxGene RNA, x3 Green Lithium Heparin tubes.</li> <li>Days 2, 4 and 6: x3 Green Lithium Heparin tubes.</li> <li>EONT: x1 PaxGene RNA, x3 Green Lithium Heparin tubes.</li> <li>Please refer to lab manual for further guidance.</li> </ul>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
12	Submit blood sample storage log	<ul style="list-style-type: none"> <li>Submit paper blood sample storage log at Day 14 to WCTU.</li> </ul>	<input type="checkbox"/>
13	Complete follow up data	<ul style="list-style-type: none"> <li>Submit Day 28 and Day 90 survival data follow up.</li> </ul>	<input type="checkbox"/>
14	Complete End of Trial PI sign off form	<ul style="list-style-type: none"> <li>Submit once instructed to by WCTU at the end of the trial.</li> </ul>	<input type="checkbox"/>

**STRESS-L Trial Participant Completion Checklist**  
**Figure 1. STRESS-L Trial Participant Flowchart**

