**Screening procedures:** [Trial ID]

|  |
| --- |
| **Weight and height** |
| Volunteer must remove his/her shoes and all heavy items of clothing or items in pockets before being weighed.  Ensure the scale reads ‘zero’ before weighing the patient. Use the same scale for all volunteers at all time-points during the study.  Record the weight to one decimal place directly into the source document.  Volunteer must remove his/her shoes and hat before having his/her height measured.  Record the height in cm to no decimal places directly into the source document.  Calculate the BMI using the height measured at screening:    (For example, if the volunteer weighs 60 kg and is 170 cm tall, his BMI is: 60/(1.7x1.7) = 20.8 kg/m2.)  Record the BMI to one decimal place directly into the source document.  STOP ALL SCREENING PROCEDURES AND INFORM DOCTOR IMMEDIATELY IF:   * Weight **≤50** kg * BMI **<18** or **>32** kg/m2 |
| **Vital signs** |
| Volunteer must rest for at least 5 minutes in the supine position before measuring vitals.  Measure heart rate, blood pressure and temperature in the supine position.  Record the vital signs directly into the source.  STOP ALL SCREENING PROCEDURES AND INFORM DOCTOR IMMEDIATELY IF:   * Heart rate **<40** or **>90** beats per min * Systolic blood pressure **<90** or **>140** mmHg * Diastolic blood pressure **<50** or **>90** mmHg * Temperature **< 35oC** >**37.5**oC |
| **ECGs** |
| Volunteer must rest for 10 minutes in the supine position before recording ECGs.  Apply the ECGs leads according to the Cardiabase instructions on the ECG machines.  Enter the subject and time-point data according to the Cardiabase instructions. The time-point ID is ‘SCREENING’. Use ‘x’ for blank fields.  Volunteers must rest for at least 1 minute between ECGs (triplicate ECGs). You must complete all 3 ECGs within 5 minutes.  STOP SCREENING PROCEDURES AND INFORM DOCTOR IMMEDIATELY IF:   * Heart rate **<40** or **>100** beats per min * PR **<100** or >**220** msec * QRS **>110** msec * QT **>500** msec * QTcF **>450** mec |
| **Safety blood sampling** |
| Check that you have the correct tubes: 2 yellow-tops; 1 purple-top; and 1 grey top.  Collect blood into the tubes in this order: yellow → purple → grey.  Record the time of sampling directly into the lab form.  Check that the tube is labelled with the correct time-point and subject number.  Complete and sign the lab request form. |
| **Safety and drugs of abuse urine sampling** |
| Ask the volunteer to provide two mid-stream urine samples. One volunteer to go to the bathroom at a time, escorted to the door by staff.  Check that the two containers are labelled with all the required fields.  Complete and sign the lab request forms for both samples. |