SOP number	**17.003**	Version	**5.0**
Title	**Research Participant's Clinical Measurements**		

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SOP category	17 NHS GG&C Clinical Research Facility – Clinical

Staff category

Staff Category	R	A	C	I
Nursing	X			
Administration	X			
GCRF Manager		X		
GCRF Associate Director				X
Senior R&I Manager				X

1. Scope

This SOP applies to all clinical staff in GCRF.

2. Purpose

The purpose of this SOP is to describe the process to obtain accurate clinical measurements from research participants within GCRF.

3. Procedures

Clinical staff are expected to comment on all vital sign changes in a patient's health record and escalate those with clinical significance. Protocol specific requirements should be followed i.e. taken sitting or supine.

3.1 Recording respiratory rate

- Ensure the participant is comfortable, either lying or sitting, and at rest.
- Take the pulse for 1 minute, hold wrist for 1 minute longer while taking respiratory rate. If the patient knows respirations are being assessed this can affect the rate. Count the respiratory rate for 1 minute to fully assess the rate, depth and rhythm.
- If the respiration rate is >25 or <8 then the participant may need medical attention (National Early Warning Score NEWS). If there are any abnormal results, notify the appropriate clinician or investigator.
- Record respiratory rate in study specific documentation and participant's health record.

3.2 Measurement of Pulse Oximetry

- Ensure Pulse Oximetry (PO) equipment is clean.

- Ensure the participant is comfortable, either lying or sitting, and at rest. Attach probe to the participant's finger, ear or toe; the clinician should assess where to attach the probe to obtain the optimum reading.
- Ensure the probe is positioned correctly and is not too tight or too loose as this could give a false reading.
- The reading will be displayed on the pulse oximeter monitor.
- When measuring PO, consider the participant's perfusion, temperature and an existent cardiac issues (WHO, PO Manual). If there are any abnormal results, notify the appropriate clinician or investigator.
- Record the result in study specific document and participant's health record.
- Clean and turn off equipment.

3.3 Measurement of temperature using Tympanic thermometer

- Ensure thermometer is clean.
- Ensure participants with removable hearing aids remove the aid at least 10 minutes prior to recording.
- Attach new single-use cover to probe tip.
- Activate the thermometer as per manufacturer's instructions.
- Gently insert the probe tip into participant's ear canal creating a seal at the opening. Align the probe with the direction of the ear canal and press scan button.
- Hold the thermometer in place until temperature reading is displayed.
- Repeat if necessary, waiting a minimum of 5 minutes before taking a further reading.
- Remove the thermometer from the participants' ear and discard the probe tip cover in clinical waste.
- Record the temperature displayed in study specific documentation and participant's health record.
- Clean and turn off equipment.

3.4 Measurement and recording of height

- A stadiometer should be used to measure height.
- Request participant remove shoes, if able to do so before measurement is taken.
- Instruct participant to stand as tall as possible with back against the vertical scale. Lower the horizontal measure to touch the top of the head. Take a reading in metres/centimetres.
- Record the height in study specific documentation and participant's health record.

3.5 Measurement of weight

- Calibrated weighing scales must be used.
- Prepare weighing scales as per manufacturer's instructions.
- Request participant remove shoes, if able to do so and outdoor clothing before measurement is taken.
- Weight should be measured in kilograms unless otherwise specified in the study protocol.
- Bioimpedance measurement should not be carried out on pregnant women and participants with cardiac pacemaker.
- Record the weight in the study specific documentation and participant's electronic health record.

3.6 Calculation of Body Mass Index (BMI)

- Accurate height and weight measurements must be obtained following sections 5.4 and 5.5.
- Calculation of BMI is the following equation:

$$BMI = \frac{\text{Weight (kg)}}{\text{Height (m)} \times \text{Height (m)}}$$

- Record the BMI in the study specific documentation and participant's health record.

4. Referenced documents

- National Early Warning Score (NEWS)
- World Health Organisation: Pulse Oximetry Training Manual

5. Related documents

None

6. Document history

Version	Date	Description
1.0	22/11/07	Release of Version 1
2.0	25/11/13	Periodic Review
3.0	15/07/16	SOP restructure Updated to template v1.4. Change of SOP title Changed approved and released by Merged a number of SOPs Minor admin changes
4.0	18/10/19	Amendment to respiratory rate guidance
5.0	18/10/2023	Update to SOP template v2.0 Change in title from Research Participants Vital Signs Minor admin changes