SOP number	**17.003**	Version	**6.0**
Title	**Research Participant's Clinical Measurements**		

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SOP category	17 NHSGGC Clinical Research Facility – Clinical

Staff category

Staff Category	R	A	C	I
Nursing	X			
Administration	X			
Principal Investigator	X			
Clinical Research Fellow	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 or abnormalities in a patient's health record and escalate those with clinical significance. Use a NEWS2 score

Protocol specific requirements should be followed i.e. patient positioning, timings etc.

Before performing any of the tasks below ensure the following:

- Seek consent from participant
- Participant is comfortable, either lying or sitting, and at rest, taking into account any instructions from sponsor about rest time
- Perform appropriate hand hygiene
- Ensure equipment is clean
- Confirm participants identity
- Always clean equipment after use

NB if patient is in for a longer visit, requiring multiple sets of observations, consider using a NEWS2 chart

3.1. Recording respiratory rate and radial pulse

- Using 2 or 3 fingers feel for pulse at the radial styloid

- Measure the pulse for 1 minute
- Continue to hold wrist and count the respiratory rate for 1 minute to fully assess the rate, depth and rhythm.
- If the participant knows respirations are being assessed this can affect the rate.
    - Normal heart rate is between 51-90 beats/minute
    - Normal respiration rate is between 12-20 breather/minute
- If out with these parameters the participant may need medical attention, notify the appropriate clinician or investigator
- Record respiratory rate and pulse in study specific documentation and participant's health record.

3.2. Measurement of Pulse Oximetry (Sp02)

- Attach probe to the participant's finger, ear or toe; the clinician should assess where to attach the probe to obtain the optimum reading.
    - Nail polish can affect readings, so finger should not be used if participant is wearing nail polish
- 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 any existent cardiac issues (WHO, PO Manual). If there are any abnormal results, notify the appropriate clinician or investigator.
    - Normal Sp02 is 96% or over. Clinical documentation should be in place is using an altered scale for SP02 readings e.g. COPD patients.
- Record the result in study specific document and participant's health record.

3.3. Measurement of temperature using Tympanic thermometer

- Ensure participants with removable hearing aids remove the aid at least 10 minutes prior to recording.
- Attach new single-use cover to probe tip.
- 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
- Record the temperature displayed in study specific documentation and participant's health record.

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 health record.

3.6. Calculation of Body Mass Index (BMI)

- Accurate height and weight measurements must be obtained following sections 3.4 and 3.5.
- 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

- World Health Organisation: Pulse Oximetry Training Manual
- **National Early Warning Score (NEWS) 2 Standardising Assessment Guideline (874) | Right DecisionsMedia_678204_smxx.pdf**

5. Related documents

- NHS Services Scotland National Infection Prevention and Control Manual

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	22/11/07	Release of Version 1	No
2.0	25/11/13	Periodic Review	No
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	No
4.0	18/10/19	Amendment to respiratory rate guidance	No
5.0	18/10/2023	Update to SOP template v2.0 Change in title from Research Participants Vital Signs Minor admin changes	No
6.0	26/10/2026	Change to prepared by and released by Transfer to new R&I SOP template v1.0 Clarified respiratory rate and radial pulse process Clarifications made to SPO2 section Updated NEWS to NEWS2	No

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