

Clinical S.O.P. No.: 6 Version 1.0

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DOCUMENT HISTORY

| Version | Detail of purpose / change | Author / edited | Date |
|---------|----------------------------|-----------------|------|
| number | | by | |
| 1.0 | New SOP | Shona Brearley | |
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S.O.P. No. 6

1. Introduction

The measurement of weight is necessary in the calculation of (BMI) of patients. Along with height, waist /hip ratio and body impedance, this can give a good measure of adiposity and central adiposity.

2. Objectives

To describe the procedure for the measurement of weight and body impedance and calculation of BMI and to promote uniformity within the SDRN in accordance with ICH GCP guidelines.

3. Responsibilities

Research staff trained in the measurement of weight/ body impedance using the equipment supplied. All equipment should be standardised throughout the centres. The recording of these measurements should be accurate and follow ICH GCP guidelines.

- Use black ballpoint pen
- Print all entries legibly

4. Equipment

- Calibrated weighing scales must be used.
- Calibrated Bioimpedance machine must be used. Remember to check contraindications for this equipment.
- All equipment must be calibrated by an independent source on at least an annual basis.

5. General points

- Inform patient of need for procedure and obtain verbal consent.
- Check with participants that they do not have a cardiac pacemaker and that females are not likely to be pregnant if biomepedance is to be measured.

6. Procedure

- Prepare weighing scales/biompedance machine as per manufacturers instructions.
- Request that participant remove any outdoor clothing and footwear i.e. coats, jackets, heavy outerwear, shoes/boots and socks/tights.
- If required, enter details of age/sex/body build & height into machine for calculation of biompedance.
- Weight should be measured in Kilogrammes.
- Weight and body impedance should be recorded in the CRF.
- The recording of these measurements should be accurate and follow ICH GCP guidelines.
- Calculation of body mass index (BMI) is by the following equation.

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