

Category: Study Procedures

Title: Measurement of Blood Pressure using a sphygmomanometer

SOP No: DCP/Ph1/010

Date first effective: 1st January 2024

Review date: 31st December 2024

For: Phase-1 Unit, 2nd Floor, Department of Clinical Pharmacology,
New MS Building, Seth GS Medical College & KEM Hospital, Parel,
Mumbai 400012.

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1. Purpose:

This standard operating procedure (SOP) describes the responsibilities of the medical personnel in the Department towards procedures to be followed for Measurement of Blood Pressure using a sphygmomanometer.

2. Scope:

This SOP is limited to understanding the responsibilities of medical personnel in the study team measurement of Blood Pressure using a sphygmomanometer

3. Responsibilities

Principal investigator, Co-investigator and other medical personnel in the team, as delegated by the Principal Investigator, will be responsible for implementing this SOP.

4. Applicable rules, regulations and guidelines

- Indian GCP Guidelines 2001
- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017
- ICH E6 (R2) Integrated Addendum to ICH E6 (R1), Current Step 4 version dated 9th November, 2016
- IEC-1 and IEC-2 SOPs, Guidelines and Checklist
- The New Drugs and Clinical Trial rules. CDSCO, 2019.

5. Prerequisites for BP Measurement

1. Counsel the patient, make him/her comfortable, to remain calm and relax for 20 minutes before starting the procedure.

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2. Make the participant/ patient to sit with straight back like sitting on a chair with arm comfortably kept on arm of the chair or a table and feet resting on the ground.
3. If taken in lying down position, the arm of the participant/ patient should be rested on a pillow.
4. BP cuff should be of proper size covering 80% of width of arm and about 2/3 of the circumference.
5. The Patient/participant should be wearing loose fitting clothes, cuff should not be applied over clothes.
6. Apparatus should be kept at the eye position of the physician.
7. Recording should be at the same time in the same limb and same posture every time.
8. Patient/participant should not take alcohol/ caffeine at least 30 minutes before recording.
9. Patient/participant should not talk, laugh, sneeze or eat during the procedure and remain calm.

6. Procedure for BP Measurement

1. Any tight clothing to be loosened, so that the upper arm is accessible for the cuff.
2. Cuff should be placed over the arm 1-2 inches above the antecubital fossa so that two fingers can pass between the cuff and arm.
3. Position of the arm should be such that the cuff and heart should be at same level.
4. Tubes should be on inner side of the arm along the brachial artery.
5. Connect the cuff tubing to sphygmomanometer to start recording the BP.
6. The apparatus should be at levelled surface to avoid tilt.
7. Place the stethoscope in the antecubital fossa and listen for the pulse.
8. Inflate the cuff and stop as soon as the pulse disappears.

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9. Wait for a moment to ensure no pulse, then start deflating. The reading at the sphygmomanometer when the pulse reappears is the systolic BP.
10. Deflate further until the pulse disappears, this is recorded as diastolic BP.
11. Deflate completely, take at least two readings at two minutes interval.
12. Readings should be taken in lying down, sitting and standing position to rule out any postural hypotension.

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