

ALL OF US RESEARCH PROGRAM

Standard Operating Procedure Heart Rate Measurement

SOP Number 013
Effective Date

Version 4
6/26/17

1.0 SCOPE

1.1 INTRODUCTION AND PURPOSE

- 1.1.1 The purpose of this procedure is to obtain the heart rate for the required physical exam for all study participants.

2.0 PROCEDURES

2.1 MATERIALS

- Digital (oscillometric automatic device) blood pressure device, with a variety of cuff sizes is required. A manual heart rate may be taken in the event of a digital equipment failure. Manual pulse determination should be taken 3x, 1 minute apart and the measurement should be documented in HealthPro. (see method below section 11)
- Clock or watch with second hand
- HealthPro (documentation tool)

2.2 RESPONSIBILITY

- Research coordinators, nurses and other trained Program staff assigned to complete heart rate measurement.

2.3 PROCESS

The following steps should be taken to complete the heart rate measurements for each participant. (Note: steps 1-7 are identical to BP SOP)

1. Assure participants are sitting still in a chair with back support, legs uncrossed and feet flat on the floor, resting comfortably for at least 5 minutes prior to BP/heart rate measurement.
2. Use of right arm is preferable. If right arm cannot be used (e.g. Amputations, Mastectomy, etc.) the left arm may be used. Select which arm is used in HealthPro (dropdown). If right or left arm not available, no other extremities should be used. Document protocol modification in HealthPro.
3. Ask participant to breathe in and out slowly in a relaxed fashion.
4. Participant arms should be relaxed at the sides or the arm should be resting at the level of the heart supported by a table.
5. Participant's upper arm should be bare and free of constrictive clothing.
6. The participant and the trained Program staff should not talk during the measurement process.

ALL OF US RESEARCH PROGRAM
Standard Operating Procedure
Heart Rate Measurement

SOP Number 013
Effective Date

Version 4
6/26/17

- The cuff should be applied according to the manufacturer's instructions to the bare arm. The artery indicator line should be positioned over the brachial artery. When the cuff is wrapped around the participant's arm, the indicator on the outer edge of the flap should fall between the size guidelines on the cuff.
- Heart rate measurement will be displayed on the blood pressure cuff screen at the same time as the final blood pressure measurement. The 2nd and 3rd measurements will be averaged when entered into HealthPro.

The screenshot displays three individual blood pressure readings in a grid format. Each reading includes fields for Systolic, Diastolic, and Heart Rate measurements, along with an 'Irregular Heart Rate' checkbox. Below the readings is a blue header for the 'Average' section, which provides the mean values for the last two readings.

Reading #1	Reading #2	Reading #3
Systolic: 120 mmHg	Systolic: 121 mmHg	Systolic: 118 mmHg
Diastolic: 80 mmHg	Diastolic: 78 mmHg	Diastolic: 77 mmHg
Heart Rate: 70 bpm	Heart Rate: 68 bpm	Heart Rate: 66 bpm
<input type="checkbox"/> Irregular Heart Rate	<input type="checkbox"/> Irregular Heart Rate	<input type="checkbox"/> Irregular Heart Rate

Average
Blood pressure: **119.5 / 77.5** mmHg (average of 2nd and 3rd measures)
Heart rate: **67.0** bpm (average of 2nd and 3rd measures)

9. If two consecutive out-of-range values are entered for heart rate an alert will be displayed in HealthPro, prompting an action by the staff. Site specific SOPs or guidelines of the core protocol for emergent and urgent care referral should be followed (depending on your site's policy) including whether visit should be terminated. If the visit is terminated, and the participant is scheduled to complete their visit at a future date, the blood pressure and heart rate must be repeated. If the other physical measurements were completed during the first visit, the provider does not need to repeat the physical measurements that were already taken and documented in HealthPro.

Actionable Findings:

- Emergent referral**
 - Heart rate is < 60 or >100 with any symptoms of hemodynamic instability
 - Heart rate is < 60 or >100 with hypotension (SBP <90 mmHg without symptoms of hemodynamic instability)

ALL OF US RESEARCH PROGRAM
Standard Operating Procedure
Heart Rate Measurement

SOP Number 013
Effective Date

Version 4
6/26/17

- **Urgent referral**
 - Asymptomatic heart rate <50 beats per minute or >120 beats per minute
 - Irregular heart rate >100 beats per minute
 - If the heart rate is unable to be determined via digital cuff due to irregularity (following verification by manual pulse determination when possible) an alert for an urgent referral will be displayed. If the participant is aware of having an irregular heart rhythm (e.g. chronic atrial fibrillation) no referral is required.

10. Results documented in HealthPro should include: a) pulse measurement.

11. Manual Pulse Determination:

- Have the participant extend his/her arm, and take the participant's hand. Slide your index and middle finger along the thumb to the hollow of the wrist to locate the radial artery. This can be done on the left or right arm, depending on what is comfortable for you and the participant. Apply pressure with your fingertips until you can feel the participant's pulse.
- Once you feel a regular rate, count the number of beats you feel in thirty seconds. Multiply the result by two to get the participant's pulse. If the participant reports they have an irregular heart rate, you will need to count the beats for one full minute.
- The manual pulse determination should be taken 3x, one minute apart.

The image displays three sequential screenshots of a digital health measurement interface, labeled 'Reading #1', 'Reading #2', and 'Reading #3'. Each screenshot contains the following fields and elements:

- Systolic:** A text input field with a value (120, 221, 118) and a unit label 'mmHg'.
- Diastolic:** A text input field with a value (80, 78, 77) and a unit label 'mmHg'.
- Heart Rate:** A text input field with a value (70, 68, 66) and a unit label 'bpm'.
- Irregular Heart Rate:** A checkbox with the text 'Irregular Heart Rate' next to it.
- Footer:** A small blue link that says 'Add protocol modification'.

Reading #2 includes a warning message: 'This value may indicate a hypertensive crisis if confirmed by a consecutive measure.' located below the Systolic field.

3.0 LIST OF ATTACHED FORMS

None

ALL OF US RESEARCH PROGRAM
Standard Operating Procedure
Heart Rate Measurement

SOP Number 013
Effective Date

Version 4
6/26/17

4.0 REFERENCES TO OTHER APPLICABLE SOPS

Blood Pressure

5.0 REFERENCES

Recommendations for Blood Pressure Measurement in Humans and Experimental Animals.
<http://circ.ahajournals.org/content/111/5/697.long>

6.0 APPROVALS

MEDICAL DIRECTOR? Director of Operations?

DATE

REVISION HISTORY	
Original Date	Month XX, Year
Review Date	Month XX, Year
1. ----	

Effective Date	Version	Synopsis of Change
1/17/2017	1	Original Document
4/20/2017	2	<ul style="list-style-type: none"> - Section 2.1, allows manual pulse determination if automatic cuff fails. - Section 2.3 (#1) changed resting time to five minutes. - Section 2.3 (#2) added no other extremities besides arm should be used for obtaining blood pressure. - Section 2.3 (#8) removed language relating to cuff sizes and added that staff should follow device manufacturer's instructions. - Removed measurement of arm circumference and removed cuff size specifications. Replaced with measure per

ALL OF US RESEARCH PROGRAM
Standard Operating Procedure
Heart Rate Measurement

SOP Number 013
Effective Date

Version 4
6/26/17

		<p>manufacturer's instructions.</p> <ul style="list-style-type: none"> - Added additional measurements that prompt urgent referral <ul style="list-style-type: none"> ▪ Asymptomatic heart rate <50 beats per minute or >120 beats per minute ▪ Irregular heart rate >100 beats per minute ▪ Added if the heart rate is unable to be determined via digital cuff due to irregularity (following verification by manual pulse determination when possible) an alert for an urgent referral will be displayed. If the participant is aware of having an irregular heart rhythm (e.g. chronic atrial fibrillation) no referral is required. - Added manual pulse determination instructions
4/26/17	3	<ul style="list-style-type: none"> - Updated screen shot - (Section 11) Changed word patient to participant in
6/26/17	4	<ul style="list-style-type: none"> - If two consecutive out-of-range values are entered for heart rate an alert will be displayed in HealthPro, prompting an action by the staff. Site specific SOPs SOP or guidelines of the core protocol for emergent and urgent care referral should be followed (depending on your site's policy) including whether visit should be terminated. If the visit is terminated, and the participant is scheduled to complete their visit at a future date, the blood pressure and heart rate must be repeated. If the other physical measurements were completed during the initial visit, the provider does not need to repeat the physical measurements that were already taken and documented in HealthPro.