SECTION: Research and Compliance				NUMBER: CLN-26.00
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/4/2009	REV. B: 8/30/2010	REV. C:
TITLE: Obtaining Vital Signs			Page 1 of 2	

1. PURPOSE

To standardize how a study participant's (SP's) vital signs are taken.

2. SCOPE

Applies to all personnel involved in the review and implementation of clinical research investigations.

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for the accuracy of study procedures and the data recorded on all source documents and Case Report Forms (CRFs).

4. BACKGROUND

The collection of vital signs as required by the study protocol should be consistent between study visits.

5. PROCEDURE

5.1. **Vital Signs.** Investigators are expected to comment on all meaningful vital sign changes and are required to comment on those that meet criteria for clinical significance.

5.1.1. **Blood Pressure.** The BP is obtained using a sphygmomanometer and appropriate sized cuff. The cuff must be placed at least 1 inch above antecubital fossa and pulled tight around the arm. The stethoscope is placed on the brachial artery in the antecubital fossa. The level of the manometer when the first Korotkoff sound is heard is registered as the systolic pressure and the level when the fifth Korotkoff sound is heard (disappearance of all sound) is recorded as the diastolic pressure.

5.1.1.1. SP must sit or lie quietly while pressure is being taken. If indicated in the protocol, the blood pressure is to be taken in both of the following positions:

5.1.1.1.1. Supine - SP has been lying supine in a comfortable position for at least five minutes or at an alternative time given in the protocol.

5.1.1.1.2. Standing - SP has been standing for exactly two minutes after being in the supine position, or as otherwise indicated in the protocol.

5.1.1.2. Pediatric and infant BPs will be taken as indicated in the protocol.

5.1.2. **Heart Rate.** Obtained via the radial and/or apical pulse. The rate is measured for 30 seconds and recorded for number of beats/minute. Regularity of the heart rate should be noted. The heart rate may also be measured in the supine/standing positions at the same time the blood pressure is taken, as indicated by the study protocol.

5.1.3. **Body Temperature.** Temperature is measured using a digital tympanic, oral, or rectal thermometer, as required by the study protocol.

5.1.4. **Body Weight.** Body weight may be measured and recorded at screening and subsequent study visits, as indicated in the study protocol. Using a calibrated scale, weight is obtained by having the SP remove his/her shoes and heavy clothing. SP must stand still on the scale while the weight is obtained. Weight will be recorded in pounds or kilograms, as required by the study protocol.

5.1.5. **Height.** Height may be measured and recorded at screening and subsequent study visits, as indicated in the study protocol

6. TERMS & ABBREVIATIONS

BP Blood Pressure
CRF Case Report Form
PI Principal Investigator
SC Study Coordinator
SP Study Participant

7. REFERENCES

None

8. ATTACHMENTS

None