

POLICIES AND PROCEDURES

SECTION: Research and Compliance			NUMBER: CLN-24.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/4/2009	REV. B: 8/27/2010	REV. C:
TITLE: History and Physical Exam			Page 1 of 2	

1. PURPOSE

To set the standard upon which Study Participants (SPs) are evaluated by the Principal Investigator (PI) or her/his designee on the basis of the potential SP's past medical history, a physical exam, plus selected demographic information, vital signs (temperature, blood pressure (BP), heart rate, respirations), and height and weight.

2. SCOPE

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

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

3. RESPONSIBILITIES

The PI is responsible for the completeness and accuracy of the medical history and physical examination that must be performed by licensed medical and/or health practitioners as designated by the PI. She/he is also responsible for the accuracy of the demographic information and vital signs recorded on the screening forms and source documents and/or Case Report Forms (CRFs).

4. BACKGROUND

The screening exam is the first opportunity for the PI and her/his research staff to assess the safety and suitability of potential SPs for a given research study. A careful and thorough medical history and physical exam is an essential part of this process.

5. PROCEDURE

5.1. Equipment

- 5.1.1. Proper examination room with an exam table, lighting, stethoscope, blood pressure (BP) sphygmomanometer, otoscope, ophthalmoscope, percussion hammer, neurological testing equipment, barrier gloves, a scale, digital thermometer device, and blood drawing supplies.

6. TERMS & ABBREVIATIONS

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

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7. REFERENCES

7.1. ICH GCP Consolidated Guideline - Parts 4.2.4, 4.3.1, and 4.3.2

8. ATTACHMENTS

None