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

8. ATTACHMENTS
   None