# Standard Operating Procedures for

# Physical Examination

|  |  |
| --- | --- |
| **SOP Number**: SP-011-CT | **Effective Date**: 24-Sep-2016 |
| **Version Number and Authorization Date**: 1.0 , 03-Aug-2016 |

**Table of contents**

[1. PURPOSE 3](#_Toc166236884)

[2. SCOPE 3](#_Toc166236885)

[3. RESPONSIBLE FUNCTIONS 3](#_Toc166236886)

[4. DEFINITIONS and ABBREVIATIONS 3](#_Toc166236887)

[5. PROCEDURE 3](#_Toc166236888)

[5.1 Materials 3](#_Toc166236889)

[5.2 Measuring and recording vital signs 3](#_Toc166236890)

[5.3 Ask the patient about any clinical complaint 3](#_Toc166236891)

[5.4 General Review 3](#_Toc166236892)

[5.5 Physical examination of systems 4](#_Toc166236893)

[5.6 End the consultation 6](#_Toc166236894)

[5.7 Document information for the patient’s record 6](#_Toc166236895)

[6. REFERENCES 6](#_Toc166236896)

[7. APPENDIX 6](#_Toc166236897)

# Standard Operating Procedures for: Physical Examination

## PURPOSE

|  |
| --- |
| This standard operating procedure (SOP) describes the procedures for performing a physical examination for subjects in endTB Clinical Trial.  |

## SCOPE

|  |
| --- |
| This SOP applies to the physical examination activities conducted by health care providers at sites monitored by the endTB clinical trial. |

## RESPONSIBLE FUNCTIONS

|  |  |
| --- | --- |
| **Function** | **Activities** |
| **Site Principal Investigator (site-PI)** | * Supports the site clinical investigator and delegated site clinician in ensuring that the physical examination is performed according to the study protocol
 |
| **Site clinical investigator (Site-CI)** | * Inform the patient about all procedures of a physical examination
* Measure and record vital signs
* Ask for any clinical complaint (symptoms/signs)
* Perform the physical examination (general review plus examination of systems)
* Record the information in the source document, sign, and date it.
 |
| **Delegated site clinician** | * Measure and record vital signs
 |

## DEFINITIONS and ABBREVIATIONS

**Physical Examination:** The process by which a health care provider investigates the body of a patient for signs of disease using inspection (looking at the body), palpation (feeling with the hands), percussion (tapping with the fingers), and auscultation (listening). A health assessment also includes gathering information about a patient’s medical history and lifestyle (see ***SOP SP-010-CT Medical History Collection***).

## PROCEDURE

### Materials

1. Source document
2. Stethoscope
3. Pulse oximeter

### Measuring and recording vital signs

**Site clinical investigator** or **delegated site** clinicianshould measure and record vital signs of the patient according to SOP ***SP-005-ET Measuring and Recording Vital Signs***.

### Ask the patient about any clinical complaint

**Site clinical investigator** is recommended to follow the procedural details below:

1. Ask the patient whether s/he currently experiences, or has experienced in the last 30 days (for screening visit) or since the last visit (for baseline and follow-up visits), any clinical complaint (symptom and/or sign). Refer to Appendix 1 and 2 for a list of the most important symptoms and signs that have to be checked systematically.

For every complaint:

* + Encourage the patient to tell the story from when the complaint first started
	+ Use open questions at the start, clarifying with closed questions later
	+ Gain as much information as you can about the specific complaint. If there is pain, consider using the *SOCRATES* acronym to help gain additional information:
		- **S**ite: where exactly is the pain?
		- **O**nset: When did it start; was it constant/intermittent; gradual/sudden?
		- **C**haracter: What is the pain like (e.g. sharp, burning, tight)?
		- **R**adiation: Does it radiate/move anywhere?
		- **A**ssociations: is there anything else associated with the pain (e.g. sweating, vomiting)?
		- **T**ime course: Does it follow any time pattern/how long did it last?
		- **E**xacerbating/relieving factors: Does anything make it better or worse?
		- **S**everity: How severe is the pain? Consider using the 1-10 scale.
1. Grade every complaint from 1 to 4 according to severity.

### General Review

**Site clinical investigator** is recommended to follow the procedural details below:

1. Check the general appearance of the patient. Make note of any easily apparent features (e.g. mobility problem or deafness).
2. Review body weight and vital signs if they were recorded by the study nurse. If needed, measure vital signs again according to SOP ***SP-005-ET Measuring and Recording Vital Signs***. Specifically ask the patient if they are experiencing fever, cough, night sweats, shortness of breath, and hemoptysis. Use the Socrates acronym for all positive signs.
3. If the patient has shortness of breath, measure the blood oxygen saturation with the pulse oximeter. Pulse oximetry is used to measure the level of blood oxygen saturation by exploiting the light absorptive characteristics of hemoglobin and the pulsating nature of blood flow in the arteries. In order to perform pulse oximetry, first of all clean the site of the application of the probe. Probes are usually placed on the finger, but they can also be placed on the earlobe. Then attach the probe, and turn the oximeter on. If a finger probe is used, the hand should be rested on the chest at the level of the heart. This helps to minimize any motion. Record the measurement.
4. Grade every complaint
5. Check for jaundice (yellow discoloration of the skin and sclerae), anemia (pale color of skin or conjunctiva), cyanosis (blue coloration of lips or extremities), clubbing of fingernails, and oedema of ankles, lymph nodes of neck, armpits, and groins.

### Physical examination of systems

Physical examination of systems will vary according to the timing of the consultation:

* Baseline visit: Full physical exam is required for all systems listed below.
* Screening and follow-up visits: A physical examination of cardiovascular, respiratory, and abdominal systems, and a focused examination of any system to which the patient has or previously had a complaint (symptom-driven) is indicated.

In any case, the list of examinations is not exhaustive. The site clinical investigator will perform additional examinations of any concerned system if needed and eventually consult specialists.

**Site clinical investigator** is recommended to follow the procedural details below:

1. Cardiovascular
	* Check blood pressure, pulse, and rhythm.
	* Check presence of jugular vein distension, peripheral oedema, and evidence for pulmonary oedema.
	* Perform cardiac exam using stethoscope and auscultate for extra heart sounds, systolic and diastolic murmurs.
2. Respiratory
	* Observe the rate, rhythm, depth, and effort of breathing.
	* Inspect the neck for the position of the trachea, supraclavicular retractions and contraction of the sternomastoid or other accessory muscles during inspiration.
	* Auscultate the anterior and posterior chest for normal breath sounds and any adventitious sounds (crackles or rales, wheezes, and rhonchi).
		1. If abnormalities are identified, evaluate for transmitted voice sounds. In addition, palpate the chest to assess for tactile fremitus, and percuss the chest to assess for areas of dullness.
3. Head and Neck
	* Inspect head, neck, ears, nose and throat.
		1. Head: The hair, scalp, skull, and face are examined.
		2. Neck: The lymph nodes on both sides of the neck and the thyroid gland are palpated.
		3. Ears: Inspect external structures. An otoscope may be used to inspect internal structures.
		4. Nose: The external nose is examined. The nasal mucosa and internal structures can be observed with a penlight and nasal speculum.
		5. Throat: The lips, gums, teeth, roof of mouth, tongue, and pharynx are inspected. Look for signs of oral thrush, periodontitis, or any other mouth lesion.
	* If lesions are present, note their location and distribution (diffuse or localized), arrangement (linear, clustered, annular, patch), type (macules, papules, vesicles) and color.
4. Abdominal
	* Inspect and auscultate the abdomen.
		1. Listen for bowel sounds in the abdomen before palpating it.
		2. Palpate the abdomen in all four quadrants lightly and then deeply.
	* Assess the size of the liver, spleen, and kidneys.
		1. Look for pain when you press the right upper side of the liver.
	* Assess for peritoneal inflammation – look for localized and rebound tenderness, and voluntary or involuntary rigidity.
5. Dermatological
	* Inspect the skin for color, turgor, moisture, and lesions.
	* If lesions are present, note their location and distribution (diffuse or localized), arrangement (linear, clustered, annular, dermatomal), type (macules, papules, vesicles), and color.
6. Musculoskeletal
	* Check for any deformity, pain, lumps, or weakness.
	* With patient standing, note the straightness of the spine and alignment of the legs and feet.
7. Lymphatic
	* Check for adenopathy (sub-maxillary, cervical, axillary, and inguinal).
		1. Measure the adenopathy.
8. Breasts
	* The breasts are palpated and inspected for lumps or mastitis.
9. Neurological
	* Assess patient’s general alertness and mental ability during conversation.
	* Perform global assessment of higher functions.
	* Assess muscle strength, tone, and signs of rigidity.
	* Check for meningeal signs.
	* Check for the presence of disorders of balance or motor coordination.
10. Mental
	* Assess mental health condition of the patient: anxiety, depression, agitation, hallucination, nightmares, dreams, insomnia, dizziness, etc.

### End the consultation

**Site clinical investigator** is recommended to follow the procedural details below:

1. When you are satisfied that you have completed the physical examination, tell the patient you have finished
2. Check that the patient has nothing more to add
3. Summarize the information and check that it is complete and accurate
4. Thank the patient

### Document information for the patient’s record

**Site clinical investigator** is recommended to follow the procedural details below:

1. Record the information on the source document
2. Sign and date the source document

## REFERENCES

* The Inserm-ANRS SOP for Physical Examination
* "Physical Exam." TheFreeDictionary.com. N.p., n.d. Web. 06 May 2016.

## APPENDIX

|  |
| --- |
| **Appendices & Forms for completion** |
| **Number** | **Title** |
| 1 | List of patient symptoms |
| 2 | List of patient signs |

# Standard Operating Procedures for: Physical Examination

**Appendix 1. List of symptoms**

|  |  |
| --- | --- |
|  | Cough |
|  | Hemoptysis  |
|  | Chest pain  |
|  | Fatigue |
|  | Headache |
|  | Malaise |
|  | Pruritus |
|  | Dyspnea |
|  | Palpitations  |
|  | Dysphagia/odynophagia |
|  | Nausea |
|  | Vomiting |
|  | Diarrhea |
|  | Constipation |
|  | Arthralgia |
|  | Myalgia |
|  | Tinnitus |
|  | Dizziness  |
|  | Vestibular disorders |
|  | Hearing loss |
|  | Visual change  |
|  | Seizures |
|  | Syncope |
|  | Neuro sensory disorders |
|  | Muscle strength disorders |

# Standard Operating Procedures for: Physical Examination

**Appendix 2. List of signs**

|  |  |
| --- | --- |
|  | Skin rash |
|  | Mucositis/stomatitis  |
|  | Bronchospasm |
|  | Tendon injury |
|  | Arthritis |
|  | Arrhythmias |
|  | Edema  |
|  | Ascites  |
|  | Alteration in behavior/personality/mood |
|  | Alteration of reality perception |
|  | Balance disorders  |
|  | Motor coordination disorders |
|  | Lymphadenopathy > 2 cm  |
|  | Reported fever (fever reported by the patient in the previous month, at screening, or since the previous visit, at baseline and follow-up visits) |
|  | Back pain |