

## Intake and Interval Physical Exam (Age 0-4 years)

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[Study Name/ID pre-filled]

Site Name: \_\_\_\_\_

Date Form Completed: \_\_\_/\_\_\_/\_\_\_ (mm/dd/yyyy)

Subject ID: \_\_\_\_\_

Visit: [pre-populated by database]

Body System/Sign	Classifier	Comments
<b>Ear, Nose, and Throat</b>		
Congestion/Secretions (check all that apply)	<input type="checkbox"/> None <input type="checkbox"/> Nasal congestion <input type="checkbox"/> Drooling	
Facial characteristics or deformities (check all that apply)	<input type="checkbox"/> No facial deformity <input type="checkbox"/> Midface hypoplasia <input type="checkbox"/> Prognathia <input type="checkbox"/> Roundish face <input type="checkbox"/> Prominent ears <input type="checkbox"/> Low set ears	Any abnormality with crying or smiling?
Oropharynx (check all that apply)	<input type="checkbox"/> Normal oropharynx <input type="checkbox"/> Tongue protrusion <input type="checkbox"/> High arched palate <input type="checkbox"/> Cleft lip/palate <input type="checkbox"/> Dental crowding <input type="checkbox"/> Hypertrophic tongue <input type="checkbox"/> Limited mouth opening	
Head shape	<input type="checkbox"/> Normal <input type="checkbox"/> Microcephaly <input type="checkbox"/> Macrocephaly <input type="checkbox"/> Dolicocephaly <input type="checkbox"/> Plagiocephaly	
Tracheostomy	<input type="checkbox"/> No <input type="checkbox"/> Yes	
<b>Neurologic</b>		
Ophthalmoparesis (check all that apply)	<input type="checkbox"/> No <input type="checkbox"/> Yes, vertical* (upward gaze) <input type="checkbox"/> Yes, horizontal* <input type="checkbox"/> Unable to assess  *If Yes: <input type="checkbox"/> Symmetric <input type="checkbox"/> Asymmetric <input type="checkbox"/> Incomplete <input type="checkbox"/> Complete	
CN 3: Ptosis	<input type="checkbox"/> No <input type="checkbox"/> Yes	

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Visit: [pre-populated by database]

Body System/Sign	Classifier	Comments
<b>Neurologic, Cont.</b>		
CN 7: Facial weakness with smiling or crying	<input type="checkbox"/> No <input type="checkbox"/> Yes*  *If Yes, able to bury lashes: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Poor effort <input type="checkbox"/> Unable to assess  *If Yes, smile: <input type="checkbox"/> Normal <input type="checkbox"/> Transverse <input type="checkbox"/> Poor effort <input type="checkbox"/> Unable to assess	
<b>Respiratory</b>		
Pre-verbal Speech (check all that apply)	<input type="checkbox"/> Normal <input type="checkbox"/> Babbling with correct inflection <input type="checkbox"/> Imitates sounds <input type="checkbox"/> Delayed speech <input type="checkbox"/> Unable to assess	
Post-verbal Speech (check all that apply)	<input type="checkbox"/> Normal <input type="checkbox"/> Hypophonic (soft voice) <input type="checkbox"/> Nasal <input type="checkbox"/> Dysarthric <input type="checkbox"/> Scanning <input type="checkbox"/> Apraxic <input type="checkbox"/> Stuttering <input type="checkbox"/> Unable to assess	
Chest wall deformity	<input type="checkbox"/> No abnormality <input type="checkbox"/> Pectus excavatum <input type="checkbox"/> Pectus carinatum <input type="checkbox"/> Flat chest <input type="checkbox"/> Barrel chest <input type="checkbox"/> Shield chest <input type="checkbox"/> Lower rib flaring	
Dyspnea while talking	<input type="checkbox"/> Yes* _____ <input type="checkbox"/> No  *If Yes, record the number the patient can count to before taking another breath: 0 1 2 3 4 5 6 7 8 9 10 11 1 2 13 14 15 16 17 18 19 20	

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Visit: [pre-populated by database]

Body System/Sign	Classifier	Comments
<b>Respiratory, Cont.</b>		
Breathing pattern	<input type="checkbox"/> No abnormality <input type="checkbox"/> Costal retractions <input type="checkbox"/> Recruitment of accessory muscles <input type="checkbox"/> Diaphragmatic	
Rales/rhonchi	<input type="checkbox"/> No <input type="checkbox"/> Yes	
<b>Cardiovascular</b>		
Regular rate rhythm	<input type="checkbox"/> No <input type="checkbox"/> Yes	
Murmur	<input type="checkbox"/> No <input type="checkbox"/> Yes	
<b>Abdomen</b>		
Feeding tube	<input type="checkbox"/> No feeding tube present <input type="checkbox"/> Ngtube	
<b>Musculoskeletal</b>		
Muscle mass	<input type="checkbox"/> Normal <input type="checkbox"/> Hypotrophic (atrophic) <input type="checkbox"/> Hypertrophic	
Distribution of hyper or hypotrophic change (check all that apply)	<input type="checkbox"/> No hypotrophy or hypertrophy <input type="checkbox"/> Quadriceps <input type="checkbox"/> Calves <input type="checkbox"/> Deltoids <input type="checkbox"/> Triceps <input type="checkbox"/> Biceps <input type="checkbox"/> Hands	
Are there contractures? (check all that apply)	<input type="checkbox"/> None <input type="checkbox"/> Neck, extension <input type="checkbox"/> Neck, flexion <input type="checkbox"/> Shoulders <input type="checkbox"/> Elbows <input type="checkbox"/> Wrists <input type="checkbox"/> Long finger flexors <input type="checkbox"/> Fingers <input type="checkbox"/> Hips <input type="checkbox"/> Knees <input type="checkbox"/> Ankles <input type="checkbox"/> Toes	

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Visit: [pre-populated by database]

Body System/Sign	Classifier	Comments
<b>Musculoskeletal, Cont.</b>		
Is there joint laxity?	<input type="checkbox"/> Shoulders <input type="checkbox"/> Elbows <input type="checkbox"/> Wrists <input type="checkbox"/> Distal fingers <input type="checkbox"/> Fingers <input type="checkbox"/> Knees <input type="checkbox"/> Ankles <input type="checkbox"/> No joint laxity	
Upright stance: Spine (check all that apply, then answer Cobb angle if available)	<input type="checkbox"/> Normal <input type="checkbox"/> Prior scoliosis surgery by history/surgical scar <input type="checkbox"/> Kyphosis <input type="checkbox"/> Lordosis <input type="checkbox"/> Lateral thoracic S curvature <input type="checkbox"/> Protuberant abdomen <input type="checkbox"/> Unable to assess  Cobb angle, if available: _____	
Bending: Spine	<input type="checkbox"/> Normal <input type="checkbox"/> Rigid spine, lumbar in bending <input type="checkbox"/> Rigid spine, complete in bending <input type="checkbox"/> Unable to assess	
Gait (check all that apply, then answer Quality of push off)	<input type="checkbox"/> Normal <input type="checkbox"/> Trendelenberg, waddling <input type="checkbox"/> Lordotic <input type="checkbox"/> Circumduction <input type="checkbox"/> Ataxic/spastic <input type="checkbox"/> Cervical fixation <input type="checkbox"/> Foot drop <input type="checkbox"/> Toe or heel walking <input type="checkbox"/> Unable to assess  Quality of push off: <input type="checkbox"/> Normal <input type="checkbox"/> Minimal weakness <input type="checkbox"/> Unable	

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Visit: [pre-populated by database]

Body System/Sign	Classifier	Comments
<b>Musculoskeletal, Cont.</b>		
Running	Able to attempt run: <input type="checkbox"/> No <input type="checkbox"/> Yes*  *If Yes, Acceleration: <input type="checkbox"/> Normal <input type="checkbox"/> Minimal <input type="checkbox"/> Unable to accelerate  Speed: <input type="checkbox"/> Normal <input type="checkbox"/> Minimally slow <input type="checkbox"/> Slow  Feet clear ground: <input type="checkbox"/> Normal <input type="checkbox"/> Minimal <input type="checkbox"/> Unable to clear ground  Knee elevation: <input type="checkbox"/> Normal <input type="checkbox"/> Minimal <input type="checkbox"/> Unable to elevate knees  Arm pumping: <input type="checkbox"/> Normal <input type="checkbox"/> Excessive <input type="checkbox"/> Minimal <input type="checkbox"/> Unable to pump arms	
Scarf sign (While child is lying on back, pull arm over midline to opposite side of the body, observe shoulder)	<input type="checkbox"/> Shoulder stays in place, torso moves <input type="checkbox"/> Shoulder pulled halfway to midline before torso moves <input type="checkbox"/> Shoulder moves to midline before torso moves <input type="checkbox"/> Unable to assess	Describe scarf sign:
Floor to Sitting from Prone	<input type="checkbox"/> Normal <input type="checkbox"/> Rolls to side or supine, cannot get to sitting <input type="checkbox"/> Rolls over, pushes up with both arms or other assist <input type="checkbox"/> Unable to roll and get to sitting <input type="checkbox"/> Unable to assess	

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Body System/Sign	Classifier	Comments
<b>Musculoskeletal, Cont.</b>		
Floor to Stand	<input type="checkbox"/> Normal <input type="checkbox"/> Slow movement with broad stance <input type="checkbox"/> One handed Gower's <input type="checkbox"/> Two handed Gower's <input type="checkbox"/> With furniture <input type="checkbox"/> Unable to perform <input type="checkbox"/> Unable to assess	
Reflexes	Patellar: 4+ 3+ 2+ 1+ 0 Ankle: 4+ 3+ 2+ 1+ 0 Biceps: 4+ 3+ 2+ 1+ 0 Brachioradialis: 4+ 3+ 2+ 1+ 0	
<b>Observational Muscle Strength</b>		
Roll with shoulders leading	<input type="checkbox"/> Leg comes completely over <input type="checkbox"/> Leg crosses midline <input type="checkbox"/> Leg does not cross midline	
Roll with hips leading	<input type="checkbox"/> Arm comes completely over <input type="checkbox"/> Arm crosses midline <input type="checkbox"/> Arm does not cross midline	
Reflexive pull on legs	<input type="checkbox"/> Normal, flexes hips and knees <input type="checkbox"/> Mild weakness, still flexes <input type="checkbox"/> Does not flex <input type="checkbox"/> Unable to assess	
Arm movement against gravity	<input type="checkbox"/> Normal, able to lift <input type="checkbox"/> Minimal lift <input type="checkbox"/> Unable to perform <input type="checkbox"/> Unable to assess	
Hands movement against gravity	<input type="checkbox"/> Normal, able to lift <input type="checkbox"/> Minimal lift <input type="checkbox"/> Unable to perform <input type="checkbox"/> Unable to assess	

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Visit: [pre-populated by database]

Body System/Sign	Classifier	Comments
<b>Observational Muscle Strength, Cont.</b>		
Leg movement against gravity	<input type="checkbox"/> Normal, able to lift <input type="checkbox"/> Minimal lift <input type="checkbox"/> Unable to perform <input type="checkbox"/> Unable to assess	
Feet movement against gravity	<input type="checkbox"/> Normal, able to lift <input type="checkbox"/> Minimal lift <input type="checkbox"/> Unable to perform <input type="checkbox"/> Unable to assess	
Head lag	<input type="checkbox"/> Normal <input type="checkbox"/> Mild head lag, no support needed <input type="checkbox"/> Moderate to severe head lag, support required	
Torso: Flexion	<input type="checkbox"/> Normal <input type="checkbox"/> With difficulty <input type="checkbox"/> Not able	
Grip (grasping toy)	<input type="checkbox"/> Normal <input type="checkbox"/> With difficulty <input type="checkbox"/> Not able <input type="checkbox"/> Unable to assess	
Raising arms overhead (check all that apply)	<input type="checkbox"/> Normal <input type="checkbox"/> Scapular winging, mild <input type="checkbox"/> Scapular winging, moderate- severe <input type="checkbox"/> Uses accessory muscles <input type="checkbox"/> Unable to perform <input type="checkbox"/> Unable to assess	
Wheelbarrow	<input type="checkbox"/> Normal <input type="checkbox"/> With difficulty <input type="checkbox"/> Not able, collapses <input type="checkbox"/> Unable to assess	

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Body System/Sign	Classifier	Comments
<b>Dermatological</b>		
Skin (check all that apply):	<input type="checkbox"/> Striae <input type="checkbox"/> Cigarette paper skin <input type="checkbox"/> Hyperkeratosis pilaris <input type="checkbox"/> Facial erythema <input type="checkbox"/> Keloid <input type="checkbox"/> Soft, velvet <input type="checkbox"/> Normal skin	

**Missing Value Codes:**

A = Lab or equipment failure  
 M = Ran out of time  
 N = No data  
 X = Unknown  
 E = Examiner error

O = Obsolete CRF  
 D = Not applicable  
 P = Unable to test due to permanent disability  
 T = Unable to test due to temporary condition  
 S = Scheduling problem

GENERAL INSTRUCTIONS

The physical exam is generally administered at screening and/or baseline to determine study eligibility. It may also be administered at follow-up visits to track a participant's/subject's physical status. This form should be administered to participant/subject's between the ages of 0-4 years.

Important note: For a natural history study, all elements on this form are recommended as Core (i.e., strongly recommended for CMD clinical studies to collect). For an intervention study/clinical trial, the Core data elements on this form are dependent on the needs of the study design. There is not a set of Core elements recommended.

SPECIFIC INSTRUCTIONS

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module. There is actually a single Data Dictionary for all of the Physical Exam CDEs as the two different CRF Modules for CMD physical exam share many elements.*

- **Comments** – Record any additional notes or comments relevant to the Body System/Sign result
- **Missing Value Codes** – Please use these codes for all questions where a value is requested but no value is available. The purpose of these codes is to prevent any blanks on the CRF.