

**Instructions:** Assessment of the infant at all visits should include review of the infant’s health, anthropometry, and feeding history. This detailed guide is intended to be reviewed during the initial visit where the infant is assessed by a study clinician (e.g. PPO visit). Anthropometry measurements should be tracked using the appropriate growth chart per SSP section 7. Relevant conditions identified through medical history review and infant physical exams should be source documented in the infant’s study records. Any gradable infant AEs should be reported on the **Infant Adverse Event Log** and any medications the infant is currently taking should be added to the infant’s **Concomitant Medications Log CRF**.

### General Infant Medical/Medication History

- Record the infant date of birth, sex, gestational age, and Apgars (1, 5, 10 min) at birth on appropriate source documents.
- Did your infant have to stay in an intensive care unit after birth?
- Does the infant have any medical or health problems?
- Is the infant currently taking any medications?
- Has the infant ever been hospitalized for any reason other than their birth?
- Has the infant ever had surgery?
- Has the infant been to the emergency room?

### Newborn Medical History

*After delivery, did the infant have any medical problems involving the following:  
(Note information may come through medical record review and/or discussion with mother.)*

- |   |                                       |
|---|---------------------------------------|
| • Resuscitation at delivery (needed help to start breathing/crying) | • Delayed passage of meconium         |
| • Apgar scores  | • Heart Murmur                        |
| • Premature infant  | • Breathing problems                  |
| • Did NOT get vitamin K and / or eye prophylaxis                    | • Needed oxygen or help breathing     |
| • Hypoglycemia (low blood sugar)                                    | • Needed antibiotics while in nursery |
| • Hypothermia (low temperature)                                     | • Apnea (stopping breathing)          |
| • Sepsis screening lab work (to check for infection)                | • Needed head ultrasound              |
| • Elevated Bilirubin (jaundice)                                     | • Needed ophthalmologic (eye) exam    |
| • Circumcision  | • Congenital anomalies identified     |
|   | • Any other health issues             |

### Body System Infant Medical History

Assess any significant medical problems involving the following organ/systems.

- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>• Head, Eyes, Ears, Nose and Throat (HEENT)</li> <li>• Gastrointestinal (GI)</li> <li>• Genitals (undescended tests, hypospadias, male/female/intersex)</li> <li>• Lymphatic</li> <li>• Cardiovascular</li> <li>• Liver</li> <li>• Respiratory</li> <li>• Renal Musculoskeletal</li> </ul> | <ul style="list-style-type: none"> <li>• Skin</li> <li>• Neurologic</li> <li>• Endocrine/Metabolic</li> <li>• Hematologic</li> <li>• Cancer</li> <li>• Allergies</li> <li>• Problems with weight gain</li> <li>• Any other health issues</li> </ul> |
|---|---|

### Anthropometry

Record the following on the appropriate source documentation and growth chart.

Record the following **from delivery records**:

- Birth weight
- Birth length
- Birth head circumference

Additionally, measure and record the following:

- Current weight
- Current length
- Current head circumference

### Feeding History\*

Discuss the following aspects of the infants feeding history

*\*Note: Details on breastfeeding exclusivity, weaning, and complementary foods/formula should be captured through administration of the **Infant Feeding Assessment CRF***

**If the baby is breastfeeding:**

- How often is the baby feeding now?
- Does the infant have any issues with breastfeeding (e.g. trouble sucking or latching) or any special needs or medical problems that might affect feeding?
- Does the mother have any issues with milk supply or other challenges (sore/cracked/bleeding nipples, clogged ducts, mastitis) or any medical problems preventing breastfeeding?
- Any other issues?

**If the baby is receiving formula or complementary foods:**

- How much formula is the baby taking (frequency of feeding, volume)?
- Is a consistent supply of clean water and sufficient sterilizing equipment (e.g. pots to boil water) available?
- If the baby has started complementary foods (e.g. around 6 months old), what solids is the baby being fed and how often?
- Any other issues?