**Height (or length) and Weight**

Date performed1:

1. Height (or length)1: m Unknown
2. Weight1: kg Unknown

**Pulse and Blood Pressure**

Date performed2:

Time performed2: Unknown

1. Position during testing2: Sitting Supine Unknown
2. Devices in use during testing2:

Abdominal binder Pressure stockings None Unknown

1. Pulse: *XX* beats per minute (bpm)2: Regular Irregular
2. Blood pressure2: mm/Hg
3. Mean arterial pressure measurement: mmHg

**Temperature**

Date performed3:

Time performed: Unknown

1. Method used3:  Rectal Ear Oral Axilla Unknown
2. Temperature measured3: °C

**Pulmonary Function Tests**

Date performed4:

1. Forced vital capacity (FVC)4: Liters
2. Forced expiratory volume in one second (FEV1)4: Liters
3. Peak expiratory flow (PEF)4: Liters/minute
4. Oxygen saturation: (%)

**Blood Tests (Fasting Serum Lipid Profile)**

Date performed1:

1. During anti-lipid therapy1: Yes No Unknown
2. Total cholesterol (TC)1 mg/dL
3. Triglycerides (TG)1 mg/dL
4. HDL cholesterol1 mg/dL
5. LDL cholesterol1 mg/dL

(TC, HDL or LDL cholesterol: mmol/L x 39 = mg/dL; TG: mmol/L x 89 = mg/dL)

**Bowel X-Ray Investigation**

Date performed5:

1. Total gastrointestinal or colonic transit time5:

days hours  Not tested

1. Right colonic transit time5

days hours  Not tested

1. Left colonic transit time5

days hours  Not tested

**Urinary Tract Imaging**

1. Intravenous pyelography / Urography or CT urogram, or Ultrasound of the urinary tract6

Date performed:

1. Method used:

Intravenous pyelography / Urography

CT urography

Ultrasound of the urinary tract

1. Result:

Normal

Stasis/dilatation in upper urinary tract: Right side Left side

Kidney stone: Right side Left side

Stone in ureter: Right side Left side

Bladder stone

Other findings:

1. X-ray of the urinary tract – Kidney Ureter Bladder (KUB)6

Date performed:

Normal

Kidney stone: Right side Left side

Stone in ureter: Right side Left side

Bladder stone

Other findings:

1. Renography6

Date performed:

1. Method used:

DMSA (Technetium-99m dimercaptosuccinic acid)

DTPA (Technetium-99m diethylenetriaminepentaacetic acid)

Mag 3 (Technetium-99m mercaptoacetyltriglycine)

1. Result:

Normal

Excretory function: Right side % Left side %

Stasis/dilatation in upper urinary tract: Right side Left side

Other findings:

1. Clearance6

Date performed:

1. mL/(min. x 1.73 m2)
2. Cystogram6

Date performed:

1. Result:

Normal

Bladder stone

Vesicoureteric reflux: Right Left

Bladder diverticulum

Bladder neck at rest: Open Closed

Other findings:

1. Voiding cystogram / Micturition cystourogram (MCU) / Videourodynamic6

Date performed:

Normal

Vesicoureteric reflux: Right Left

Bladder neck during voiding: Normal Closed (dyssynergia)

Striated urethral sphincter during voiding: Normal Closed (dyssynergia)

Other findings:

## **Urodynamic Investigation**

Date performed7: Unknown

1. Bladder sensation during filling cystometry7:

Normal Increased Reduced Absent Non-specific Unknown

1. Detrusor function7:

Normal

Neurogenic detrusor overactivity

Underactive detrusor

Acontractile detrusor  
Unknown

1. Compliance during filing cystometry7:

Low (< 10 mL/cm H20) Yes No Unknown

1. Urethral function during voiding7:

Normal

Detrusor sphincter dyssynergia

Non-relaxing urethral sphincter obstruction

Not applicable

Unknown

1. Detrusor leak point pressure7 cm H2O Not applicable Unknown
2. Maximum detrusor pressure7 cm H2O Not applicable Unknown
3. Cystometric bladder capacity7 mL Not applicable Unknown
4. Post void residual volume7 mL Not applicable Unknown

## **General Instructions**

Vital signs are likely to be captured at study visits to help monitor the health of the participant/ subject and in clinical trials to help assess the safety of the intervention.

Height and weight are commonly collected at the baseline visit. Depending on the study population and/or the protocol it may or may not be appropriate to collect them on at other timepoints.

Important note: None of the data elements on this CRF Module are considered Core (i.e., strongly recommended for all spinal cord injury clinical studies to collect). All elements are supplemental and should only be collected if the research team considers them appropriate for their study.

## **Specific Instructions**

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

* Height – It is important to record the units used to measure height. Height and weight measurements can be used to calculate BMI (body mass index).
* Weight – It is important to record the units used to measure weight. Height and weight measurements can be used to calculate BMI (body mass index).
* Heart rate/ Pulse – Measure heart rate in beats per minute (bpm).
* Blood Pressure – Measure blood pressure in mmHg. Blood pressure is the ratio of systolic to diastolic.
* Mean Arterial Blood Pressure –The mean pressure of the blood within the arterial circulation. The arterial pressure may be directly measured by insertion of an intra-arterial catheter connected to a transducer. The mean arterial pressure (MAP) can be calculated by subsequent analysis of the waveform. MAP can be approximated without an invasive procedure using the following formula: diastolic pressure plus 1/3 of the pulse pressure, where pulse pressure is systolic pressure - diastolic pressure.
* Temperature method– Choose one.
* Temperature – It is important to record whether the temperature is measured in degrees Celsius (°C) or degrees Fahrenheit (°F). It may also be important to record the location where the temperature measurement was made.
* Oxygen saturation – Record the value as a percent (%)
* Please see corresponding Data Dictionary or the ISCoS [International SCI Data Sets](http://www.iscos.org.uk/international-sci-data-sets) for more information

[1International SCI Endocrine and Metabolic Function Basic Data Set](http://www.iscos.org.uk/international-sci-endocrine-and-metabolic-function-data-sets) (Version 2.0)

[2International SCI Cardiovascular Function Basic Data Set](http://www.iscos.org.uk/international-sci-cardiovascular-function-data-sets) (Version 1.1)

[3International SCI Skin and Thermoregulation Function Basic Data Set](http://www.iscos.org.uk/international-sci-skin-and-thermoregulation-function-data-sets) (Version 1.0)

[4International SCI Pulmonary Function Basic Data Set](http://www.iscos.org.uk/international-sci-pulmonary-function-data-sets) (Verion1.0)

[5International SCI Bowel Function Extended Data Set](http://www.iscos.org.uk/international-sci-bowel-data-sets) (Version 1.0)

[6International SCI Urinary Tract Imaging Basic Data Set](http://www.iscos.org.uk/international-sci-urinary-tract-imaging-data-sets) (Version 1.0)

[7International SCI Urodynamic Basic Data Set](http://www.iscos.org.uk/international-sci-urodynamic-data-sets) (Version 1.0)