

**University of Utah  
Central Data Management Coordinating Center**

**ANNOTATED ECRF FOR PUBLIC USE DATASETS**

**Development of a Quantitative Functional Status Scale  
(FSS) for Pediatric Patients**

**CPCCRN Protocol Number 004**

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**Annotations key:**

Table name

Column name followed by: # or \$*N*  
# = numeric  
\$ = character *N*= Length

Format (name)  
*Code list*

Calculated / Derived variable

Value not provided

DEMOGRAPHICS (1 of 1)

## Demographics

*Unique ID = SubjectID*

Demographics Data		Enrollment Data					
<b>Essential Identifying Info (Birthdate, Sex, Race) ---- * Indicates required fields</b>							
*Patient ID	SubjectID #	* Date of Birth (use 4 digits for year)	AgeInYears #	Estimated DOB?	Value not provided		
Initials	Value not provided	*Sex	SEX \$1	▼	*Race	RACE #	▼
Hispanic/Latino Ethnicity?	HISPANIC_ETHNICITY #	Race Other	OTHER_RACE \$50	Test Patient?	Value not provided		
Date Created	Value not provided						
<div style="border: 1px solid blue; padding: 5px; width: fit-content;">                     Ethnicity                      -1 = Hispanic or Latino                      0 = Not Hispanic or Latino                 </div>			<div style="border: 1px solid blue; padding: 5px; width: fit-content;">                     Race                      1 = American Indian or Alaska Native                      2 = Asian                      3 = Black or African American                      4 = Native Hawaiian or Other Pacific Islander                      5 = White                      6 = Unknown                 </div>				
Save		Show Printable version		Exit Demographics/Enrollment			

FSS Phase 1 Annotated PUD eCRF

PICU (1 of 2)

**PICU Patient**

Unique ID = SubjectID

SubjectID #

**PICU Patient**

Date of Current Hospital Admission	HospAdmitDay #
Date of Current PICU Admission	PICUAdmiDay #
Date of Current PICU Discharge	PICUDischargeDay #
Admission Status	AdmitStatus #
Operative Status	OperativeStatus #
Postoperative type	PostOpType #

DV6480G  
0 = Emergent admission  
1 = Scheduled admission

DV6478G  
0 = Not postoperative  
1 = Postoperative

DV6479G  
0 = Cardiac surgery  
1 = Neurosurgery  
2 = Orthopedic surgery  
3 = Transplant surgery  
4 = Trauma surgery  
5 = Other surgery

Catastrophic Event during this Hospital Admission CatEvent #

DV5107G  
1 = Yes  
2 = No  
3 = Not Available/Not Documented

Select the catastrophic event(s) that occurred during this hospital admission

Catastrophic event date	Select the catastrophic event(s) that occurred during this hospitalization	Describe other catastrophic event
CatEventDay #	CatEventType #	CatEventOther \$125
Add record		Delete record

DV6612G  
1 = Hypoxic Ischemic Encephalopathy  
2 = Spinal Cord Injury  
3 = Traumatic Brain Injury  
4 = Cardiac Arrest  
5 = Other

FSS Phase 1 Annotated PUD eCRF

PICU (2 of 2 )

**Catastrophic Event History**

History of previous catastrophic event

CatEventHx #

DV5107G  
1 = Yes  
2 = No  
3 = Not Available/Not Documented

**Select any previous catastrophic events prior to this hospitalization**

Select catastrophic event(s)	Describe other catastrophic event	Time interval since catastrophic event
CatEventHxType #	CatEventHxOther \$125	CatEventInt #
<input type="button" value="Add record"/>	<input type="button" value="Delete record"/>	

DV6612G  
1 = Hypoxic Ischemic Encephalopathy  
2 = Spinal Cord Injury  
3 = Traumatic Brain Injury  
4 = Cardiac Arrest  
5 = Other

DV6613G  
1 = Within last month  
2 = Within last six months  
3 = Within last 12 months  
4 = Greater than 12 months ago

FSS Phase 1 Annotated PUD eCRF

NONPICU (1 of 1)

**High-risk non-PICU Patient**

*Unique ID = SubjectID*

SubjectID #

**High-risk non-PICU Patient**

**Date of Current Hospital Admission** HospAdmitDay #

**Previous ICU (PICU or NICU) admission** PrevPICUAdmit #

**Admission Status** AdmitStatus #

**Operative Status** OperativeStatus #

**Postoperative type** PostOpType #

DV6477G  
1 = Yes  
2 = No

DV6480G  
0 = Emergent admission  
1 = Scheduled admission

DV6478G  
0 = Not postoperative  
1 = Postoperative

DV6479G  
0 = Cardiac surgery  
1 = Neurosurgery  
2 = Orthopedic surgery  
3 = Transplant surgery  
4 = Trauma surgery  
5 = Other surgery

**History of previous catastrophic event** CatEventHx #

DV5107G  
1 = Yes  
2 = No  
3 = Not Available/Not Documented

**Select any previous catastrophic events prior to this hospitalization**

Select catastrophic event(s)	Describe other catastrophic event	Time interval since catastrophic event
CatEventHxType #	CatEventHxOther \$125	CatEventInt #
Add record	Delete record	

DV6612G  
1 = Hypoxic Ischemic Encephalopathy  
2 = Spinal Cord Injury  
3 = Traumatic Brain Injury  
4 = Cardiac Arrest  
5 = Other

DV6613G  
1 = Within last month  
2 = Within last six months  
3 = Within last 12 months  
4 = Greater than 12 months ago

FSS Phase 1 Annotated PUD eCRF

TECHDEPENDENT (1 of 1)

**Technology Dependent Patient**

*Unique ID = SubjectID*

SubjectID #

**Technology Dependent Patient**

**Location at time of assessment** AssessLocation #

**Previous ICU (PICU or NICU) admission** PrevPICUAdmit #

**Date of last ICU (PICU or NICU) discharge** LastICUDC #

**Date of last hospital discharge** LastHospDC #

DV6614G  
 1 = Outpatient setting  
 2 = Rehab inpatient  
 3 = Chronic hospitalization (non-rehab)  
 4 = PICU

DV6477G  
 1 = Yes  
 2 = No

DV6613G  
 1 = Within last month  
 2 = Within last six months  
 3 = Within last 12 months  
 4 = Greater than 12 months ago

DV6616G  
 1 = Within last month  
 2 = Within last six months  
 3 = Within last 12 months  
 4 = Greater than 12 months ago  
 5 = Never been discharged

**History of previous catastrophic event** CatEventHx #

**History of catastrophic event**

DV5107G  
 1 = Yes  
 2 = No  
 3 = Not Available/Not Documented

Select catastrophic event(s)	Describe other catastrophic event	Time interval since catastrophic event
CatEventHxType #	CatEventHxOther \$125	CatEventInt #
Add record		Delete record

DV6612G  
 1 = Hypoxic Ischemic Encephalopathy  
 2 = Spinal Cord Injury  
 3 = Traumatic Brain Injury  
 4 = Cardiac Arrest  
 5 = Other

DV6613G  
 1 = Within last month  
 2 = Within last six months  
 3 = Within last 12 months  
 4 = Greater than 12 months ago



FSS Phase 1 Annotated PUD eCRF

FSS (1 of 3)

**Functional Status Scale (FSS)**

*Unique ID = SubjectID*

SubjectID #

Select the study arm this patient belongs to

Select the study arm this patient belongs to

FSSStudyArm #

DV6615G  
 1 = PICU patient  
 2 = High-risk non-PICU patient  
 3 = Technology dependent patient

**FSS and ABAS II Tests**

Date of FSS Test

FSSDay #

Time of FSS test (enter using 24 hour clock HHMM)

FSSTm \$4

Was the ABAS II performed

Value not provided

Enter reason ABAS II not performed

Value not provided

Date of ABAS II Test

ABASDay #

Time of ABAS II test (enter in 24 hour clock HHMM)

ABASTm \$4

**Variables from analysis dataset included in the FSS dataset:**

Variable	Format	Type	Label	Algorithm / Notes
mean_abas		#	Mean ABAS II score	This is calculated as the average (mean) score of the completed skill areas of the ABAS II. See overview document for detailed notes.

FSS Phase 1 Annotated PUD eCRF

FSS (2 of 3)

Functional Status Scale	
<b>Mental Status Classification</b>	MentalStatus #
<b>Sensory Classification</b>	Sensory #
<b>Communication Classification</b>	Communication #
<b>Motor Function Classification</b>	MotorFunction #
<b>Feeding Classification</b>	Feeding #
<b>Respiratory Classification</b>	Respiratory #
<b>Total FSS Classification Score</b>	TotalFSS #
<b>Comments on FSS assessment</b>	Value not provided

DV6476G  
1 = 1 Normal  
2 = 2 Mild Dysfunction  
3 = 3 Moderate Dysfunction  
4 = 4 Severe Dysfunction  
5 = 5 Very Severe Dysfunction

FSS Phase 1 Annotated PUD eCRF

FSS (3 of 3)

**Medications altering FSS**

Medications altering FSS

**Factors altering FSS**

Select other factors altering FSS

**Limitations on Care**

Limitations on care

**List any diagnoses as free text (not ICD-9)**

List any diagnoses as free text (not ICD-9)

DV6470G

- 1 = No ventilator support
- 2 = No chest compressions
- 3 = No ventilator support or chest compressions
- 4 = Other limitations of therapeutic options
- 5 = No limitations on care

FSSMEDS (1 of 1)

**Functional Status Scale (FSS) - Medications**

*Unique ID = SubjectID*

SubjectID #

Repeat\_instance #

**Medications altering FSS**

Medications altering FSS

MedicationsFSS #

Add record Delete record

- DV6469G
- 1 = Paralytics within previous week
  - 2 = Sedatives within 4 hours
  - 3 = Narcotics within 4 hours
  - 4 = Other pain medications within 4 hours
  - 5 = Sleeping aids within 4 hours
  - 6 = Other medications affecting functional status within 4 hours
  - 7 = No medications affecting functional status taken within 4 hours
  - 8 = Information on medications not available or not documented

**Functional Status Scale (FSS) - Factors**

Unique ID = SubjectID

SubjectID #

Repeat\_instance #

**Factors altering FSS**

Select other factors altering FSS

FactorsAlterFSS #

Add record Delete record

- DV2036G
- 1 = Arm boards preventing extremity function
- 2 = Soft or hard restraints preventing extremity function
- 3 = Bandages or casts preventing extremity function
- 4 = Other
- 5 = No other factors altering FSS
- 6 = Factors altering FSS not available or not documented

FSS Phase 1 Annotated PUD eCRF

FSS\_PI (1 of 1)

**Functional Status Scale for PI**

*Unique ID = SubjectID*

SubjectID #

**Test Date and Time**

Date of FSS Test

Time of FSS test (enter using 24 hour clock HHMM)

**Functional Status Scale**

**Mental Status Classification**

**Sensory Classification**

**Communication Classification**

**Motor Function Classification**

**Feeding Classification**

**Respiratory Classification**

**Total FSS Classification Score**

**Comments on FSS assessment**

DV6476G  
1 = 1 Normal  
2 = 2 Mild Dysfunction  
3 = 3 Moderate Dysfunction  
4 = 4 Severe Dysfunction  
5 = 5 Very Severe Dysfunction