

**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			
Essential Identifying Info (Birthdate, Sex, Race) ---- * Indicates required fields					
*Patient ID	SubjectID #	* Date of Birth (use 4 digits for year)	AgeInYears #	Estimated DOB?	Value not provided
Initials	Value not provided	*Sex	SEX \$1	<input type="button" value="v"/>	*Race
Hispanic/Latino Ethnicity?	HISPANIC_ETHNICITY #	Race Other	OTHER_RACE \$50	Test Patient?	Value not provided
Date Created	Value not provided				
			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		
			Ethnicity -1 = Hispanic or Latino 0 = Not Hispanic or Latino		
<input type="button" value="Save"/>		<input type="button" value="Show Printable version"/>		<input type="button" value="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 #

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

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

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

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

History of previous catastrophic event

CatEventHx #

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	
Mental Status Classification	MentalStatus #
Sensory Classification	Sensory #
Communication Classification	Communication #
Motor Function Classification	MotorFunction #
Feeding Classification	Feeding #
Respiratory Classification	Respiratory #
Total FSS Classification Score	TotalFSS #
Comments on FSS assessment	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	FSSDay_PI #
Time of FSS test (enter using 24 hour clock HHMM)	FSSTm \$4

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

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