PARTICIPATION TRACKING
Initial Report

REGISTRATION			
Patient Study ID	ID_PT	**Initials**	INIT
Consent Date	CONSENT_DT	**Consent to future contact?**	1 ☐ Yes 0 ☐ No 2 ☐ Not marked FUTURE_CON
Date of Visit	VISIT_DT		
Site	☐ UMinn (02) ☐ DFCI (03) ☐ Stanford (04) ☐ NWChildren's (05) ☐ Vanderbilt (07) ☐ MCW (08) ☐ Wash U (09) SITE ☐ Moffitt (10) ☐ Univ of Mich (16) ☐ Mem Sloan Kett (17)	**Case Type**	1 or 0 ☐ Control CASE_CTRL 1 or 0 ☐ Incident CASE_INC 1 or 0 ☐ Prevalent CASE_PREV
		Age	1 ☐ Adult (18+) 2 ☐ Ped (2-17) ADULT_CHILD

DEMOGRAPHIC INFO FROM CLINICAL REGISTRATION SYSTEM			
Age	AGE_REG	**Gender**	0 ☐ Male 1 ☐ Female FEMALE_GEN_REG
Race	1 ☐ Black 2 ☐ American Indian/Alaskan Native 3 ☐ Asian 4 ☐ Native Hawaiian/Pacific Islander 5 ☐ White RACE_REG 6 ☐ Multi 7 ☐ Unknown 8 ☐ Other, specify: _____ RACE_OTH	**Hispanic?**	1 ☐ Yes 0 ☐ No HISP_REG
		Participation Notes:	PARTIC_NOTE

Abstraction from Medical Chart
Baseline Data – Transplant Characteristics

Patient Initials		**Study ID**	
Date of Transplant ❑ DB	TX_DT	**CIBMTR Universal ID**	CIBMTR_ID
Hypertension pre-tx	❑ Yes 1 ❑ No 0	❑ Unknown -1	HYPERT
Height pre-tx ❑ DB	HT & HT_UNIT 1=cm 2=in	**Weight pre-tx** ❑ DB	WT_PRE WT_PRE_UNIT 1=Kg 2=lb
Full PFT pre-tx ❑ DB PFT_PRE	❑ 0 Not performed ❑ 1 Report attached	**PFT with bronchodilation?** ❑ DB	❑ Yes ❑ No DIL_PRE
Full Volume Capacity (FVC) ❑ DB		FVC_L_PRE L	FVC_PRE % predicted
FEV-1 ❑ DB		FEV1_L_PRE L/sec	FEV1_PRE % predicted
Single breath DLCO (adjusted for Hemoglobin) ❑ DB		DLCO_PRE	% predicted
Age of Patient at Tx ❑ DB	AGE_TRANS	**Age of Donor** ❑ DB	DNR_AGE

Disease Status ❑ DB		**Early**	**Intermed.** DIS_STATUS	**Adv.**
DIS_DX	AML 1	❑ CR1 100	❑ CR2 101	❑ CR3+, rel, ref, IF 102
	ALL 2	❑ CR1 200	❑ CR2 201	❑ CR3+, rel, ref, IF 202
	CML 3	❑ CP 300	❑ AP 301	❑ BC or after BC 302
	CLL 4		❑ CR, PR, CS 401	❑ Rel, ref, CI 402
	MDS 5	❑ RA, RARS 500	❑ RAEB, RAEBT 501	❑ Rel, ref, IF 502
	NHL 6		❑ CR, PR, CS 601	❑ Rel, ref, CI 602
	HD 7		❑ CR, PR, CS 701	❑ Rel, ref, CI 702
	MM 8		❑ CR, PR, CS 801	❑ Rel, ref, CI 802
	AA 9	❑ Without ATG/TG 900	❑ With ATG/TG 901	
Other, spec: 10		❑ Early (non-malig) 1000	❑ Intermed. (CR, PR) 1001	❑ Adv. (Rel, ref, CI) 1002

Transplant Source ❑ DB SOURCE	❑ Peripheral Blood 1 ❑ Bone Marrow 2 ❑ Cord Blood 3	**CMV antibodies?** ❑ DB	
Transplant Type ❑ DB TX-TYPE	❑ Myeloablative 1 ❑ Non-myeloablative 2	❑ 1 Yes -- Patient ❑ 0 No -- Patient PT_CMV	❑ 1 Yes -- Donor ❑ 0 No -- Donor DNR_CMV

Donor Gender ❑ DB DNR_GEN *(choose 2 genders if double cord)*	❑ 0 Male ❑ 1 Female ❑ 2 Female/Female ❑ 3 Male/Male ❑ 4 Male/Female	**Donor Match** DNR_MATCH ❑ DB	❑ 2 HLA-identical sibling ❑ 3 HLA-matched other relative ❑ 4 HLA-mismatched relative (1 antigen mismatched) ❑ 8 Haploidentical relative (≥2 mismatched) ❑ 6 Matched Unrelated Donor ❑ 7 Mismatched Unrelated Donor

Preparative Regimen ❑ DB	**GVHD prophylaxis** ❑ DB
PREP_RX	PROPHY

❑ DB	**Maximum Acute GVHD Grade** ❑ DB					
Date of Acute GVHD Diagnosis	**Overall**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4 AGVH_OVER
AGVHD_DT	**Liver**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4 AGVH_LIV
	GI	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4 AGVH_GI
~~❑ No Acute GVHD~~	**Skin**	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4 AGVH_SKIN

if checked date = 1/1/60 scores = 0

Abstraction from Medical Chart
Baseline Data – Transplant Characteristics

Instructions for GVHD Therapy
List: steroids, immunosuppressants, and other GVHD therapy
Please see the Data Entry FAQ for a complete list
If steroid, give max dose

THERAPY GIVEN FOR ACUTE GVHD
from acute diagnosis date:_____ to
enrollment:_____

❑ Not applicable, no acute GVHD

Steroid	Max Dose For Acute	Other GVHD Therapy	Other GVHD Therapy
1. A_STER1	A-DOSE1 A_FREQ1	1. A_MED1	6.
2. ↓	↓ ↓	2. ↓	7.
3. A_↓STER3	↓ ↓	3. ↓	8.
Notes:	(also mg-kg)	4. ↓	9.
		5. A_MED5	10.

ACUTE_RX

(also protocol and none)

THERAPY GIVEN FOR CHRONIC GVHD
from chronic diagnosis date: _____ to
enrollment: _____

❑ Not applicable, date of diagnosis and enrollment are within 0-7 days apart.

Steroid	Max Dose for Chronic	Other GVHD Therapy	Other GVHD Therapy
1. MAX_STER1	MAX_DOSE1 MAX_FREQ1	1. INT_MED1	6.
2. ↓	↓ ↓	2. ↓	7. ↓
3. ↓	↓ ↓	3. ↓	8.
Notes:	(also mg-kg)	4. ↓	9. ↓
		5. ↓	10. INT_MED10

CHRONIC_RX

(also protocol and none)

CODED MEDS FOUND IN FIRST RECORD IN CHART REV VISIT TABLE
(Baseline = true)

Abstraction from Medical Chart
Baseline Data – Chronic GVHD

Patient Initials		Study ID	

CHARACTERISTICS OF CHRONIC GVHD AT ONSET

Acute GVHD present the week before chronic GVHD diagnosis? ONSET	☐ Yes ☐ No	**Was chemotherapy given after transplant for treatment of a hematologic malignancy?** CHEMO	☐ Yes ☐ No
Date of chronic GVHD diagnosis GVHD_DT		**Date of PFT** *(+/- 2 mo from date of cGVHD dx)* PFT_ODT	
Full PFT PFT_O	☐ Not performed ☐ Report attached	**PFT with bronchodilation?** DIL_O	☐ Yes ☐ No
Full Volume Capacity (FVC)	FVC_L_O L	FVC_O	% predicted
FEV-1	FEV1_L_O L/sec	FEV1_O	% predicted
Single breath DLCO (adjusted for Hemoglobin)	DLCO_O % predicted	**Weight** WT_O	☐ Kg 1 ☐ Lb 2 (WT_O_UNIT)
Karnofsky or Lanksy performance score	KPS_O LPS_O %	**Percent BSA** BSA_O	%
Lichen-planus-like changes of Skin LICH_O	☐ Yes	☐ No	☐ Unknown
Sclerotic changes of Skin SCL_O	☐ Yes	☐ No	☐ Unknown
Chronic diarrhea DIA_O	☐ Yes	☐ No	☐ Unknown
Oral involvement ORAL_O	☐ Yes	☐ No	☐ Unknown
Total bilirubin BILI_O mg/dL		**Platelet count** PLT_O	k/uL

For all medications below:
List steroids, immunosuppressants & other GVHD therapy
If steroid, give max dose

Immunosuppression
Given from 7 days before date of chronic diagnosis: to date of chronic diagnosis:

IMMSUPP

Initial therapy
Given from date of chronic diagnosis: to 7 days after chronic diagnosis:
Confirm that therapy was actually given, not just recommended

INITIAL_THER

Study ID: _____

Comorbidities in cGVHD Scale

(Adapted from Sorror Scale and Functional Comorbidity Index)

A comorbidity is a co-existing medical condition that is **active** (i.e. documented by radiographic, diagnostic testing, or laboratory evidence, or requiring either periodic surveillance/evaluation or medical management, or both), whether or not it is related to chronic GVHD.

To be completed at

[ ] Enrollment Date: into chart review visit table

[ ] Chronic GVHD onset (for prevalent cases only) Date: into baseline review table

[ ] Death or Relapse Date: into chart review visit table

prefix = CMB_

prefix = CMB_ suffix = _0

Comorbidity	Definition	Present (circle)
1. CARDIOVASCULAR		
Arrhythmia	Atrial fibrillation or flutter, sick sinus syndrome or ventricular arrhythmias	A
Coronary artery disease	Coronary artery disease (one or more vessel-coronary artery stenosis requiring medical treatment, stent, or bypass graft),angina treated at any point in patient's past medical history	B
History of MI	History of myocardial infarction	C
Heart valve disease	Except asymptomatic mitral valve prolapse	D
Hypertension	Requiring treatment	E
Congestive heart failure	EF≤50%	F
Cerebrovascular disease	Transient ischemic attack or history of cerebrovascular accident, or neurologic impairment consequent to CVA	G
Peripheral vascular disease		H
Venous thrombosis	Confirmed radiographically and requiring anticoagulation	I
2. GASTROINTESTINAL		
Peptic ulcer/hernia/reflux	Requiring treatment, including preventative treatment	J
Mild hepatic	Chronic hepatitis, bilirubin >ULN to 1.5 x ULN, or AST/ALT>ULN to 2.5 x ULN	K
Moderate/severe hepatic	Liver cirrhosis, bilirubin >1.5 times ULN or AST/ALT> 2.5 x ULN	L
Inflammatory bowel disease	Crohn's disease or ulcerative colitis	M
3. PULMONARY		
Moderate pulmonary	DLCO and/or FEV-1 66%-80% or lower; dyspnea on slight activity	N
Severe pulmonary	DLCO and/or FEV-1 65% or lower; dyspnea at rest or requiring oxygen	O
Asthma	Asthma symptoms for which inhaled steroids or other daily treatments are needed chronically to prevent or manage attacks	P
4. ENDOCRINE		
Diabetes	Requiring treatment with insulin or oral hypoglycemic agents but not diet alone	Q
Hypothyroidism	Including compensated hypothyroidism	R
Adrenal Insufficiency	Including compensated adrenal insufficiency	S
5. NEUROPSYCHIATRIC		
Psychiatric disturbance-Depression	Depression requiring psychiatric consult or treatment	T
Psychiatric disturbance-Anxiety or panic disorder	Anxiety or panic disorder requiring psychiatric consult or treatment	U

CMB_ARR

CMB_CAD

MI

HVD

HTN

CHF

CVD

PVD

VT

ULC

HEPM

HEPS

IBS

PULMM

PULMS

AST

DB

HT

AI

DEP

ANX

CMB_ARR_0

CMB_CAD_0

Study ID: _____

	Comorbidity	Definition	Present (circle)
ND	Neurologic disease (peripheral neuropathy, MS, Parkinson's disease or other chronic neurologic disease)	Symptomatic and requiring treatment to control or manage symptoms/disease process	V
VIS	Visual impairment secondary to cataracts, glaucoma or macular degeneration	Unilateral or bilateral, and unrepaired	W
EAR	Hearing impairment	Very hard of hearing, even with hearing aids	X
	6. BONE/JOINT		
OA	Osteoarthritis	Symptomatic and requiring treatment or with osteoarthritic changes noted on radiographic studies	Y
DISC	Degenerative disc disease (spinal stenosis or severe chronic back pain)	Symptomatic and requiring treatment or symptomatic and with degenerative disc disease noted on radiographic studies	Z
AVN	Avascular necrosis	Symptomatic with pain secondary to AVN or joint replacement	AA
OP	Osteopenia/Osteoporosis	T Score < or equal to minus 1.5 or on treatment with a bisphosphonate	BB
RA	Rheumatologic	Lupus, mixed connective tissue disorder, rheumatoid arthritis, polymyalgia rheumatica	CC
	7. OTHER COMORBIDITIES		
INFX	Infection	Requiring current treatment with an antimicrobial (not prophylaxis)	DD
REN	Moderate/severe renal	Serum creatinine>2 mg/dL, on dialysis, or prior renal transplantation	EE
ST	Prior solid malignancy	Treated at any time point in the patient's past history, excluding nonmelanoma skin cancer	FF

Note: BMI will be calculated from weight and height recorded elsewhere
Note: to convert creatinine from mg/dl to micromoles/L, multiple mg/dl by 88.4

Total Number of Comorbid or Secondary Conditions: _____

Abstraction from Medical Chart
At Study-Related Clinic Visit—Enrollment

Study ID	ID_PT	Initials	INIT	Date of clinic visit	VISIT_DT

DIAGNOSTIC AND LABORATORY DATA

Range of motion	☐ Not performed 0	☐ Report attached 1 ROM			
Blood Pressure	BP_SYS / BP_DIA mm/Hg	Weight	WT_RPT ☐ Kg 1 WT_RPT_UNIT ☐ Lb 2		
Full PFT	☐ 0 Not performed	☐ 1 Report attached PFT			
PFT with Bronchodilation?	☐ Yes	☐ No	☐ N/A DIL		
Full Volume Capacity (FVC)	FVC_L L	FVC %			
FEV-1	FEV1_L L/sec	FEV1 %			
Single breath DLCO (adjusted)	DLCO %				
Total WBC	WBC k/ul	Platelet count	PLT k/ul		
% Eosinophils	EOS %	% Neutrophils	NEU %		
% Lymphocytes	LYM %				
Total serum bilirubin	BILI mg/dL	ALT	ALT units/L		
Alkaline Phosphatase	ALP units/L	Albumin	ALB gm/dL		
Creatinine	CRE mg/dL	Glucose	GLU mg/dL		

Instructions for lipid panel and urinalysis: Scan interval between study visits. Ok if missing (write -1). For enrollment: first choose up to 2 mo prior, if not, then 1 mo post

Date of lipid panel	LIPID_DT	Date of urinalysis	URINE_DT
Fasting for lipids?	FAST ☐ Yes	☐ No	☐ Unknown
Cholesterol	CHOL mg/dL	Triglycerides	TRIG mg/dL
LDL	LDL mg/dL	HDL	HOL mg/dL
Urine creatinine/microalbumin	MICRO URN mg/g creatinine		

Blood in Urine (Dipstick) URINE_BLOOD	-88 ☐ Not done	0 ☐ 0	9 ☐ Tr	☐ 1+ 1	☐ 2+ 2	☐ 3+ 3	☐ 4+ 4
Protein in Urine (Dipstick) URINE_PROTEIN	☐ Not done	☐ 0	☐ Tr	☐ 1+	☐ 2+	☐ 3+	☐ 4+

Current Medications' Dose Regimens

List dose regimen of antibiotics, steroids, immunosuppressants & other GVHD therapy that the patient is currently taking. Do not include dosage changes prescribed on today's visit.

MEDS_CURRENT

Abstraction from Medical Chart
At Study-Related Clinic Visit—Enrollment

ENROLLMENT DATA ONLY					
Has a DLI been given between transplant and enrollment?	☐ Yes DLI ☐ No			**If yes, date of most recent DLI before enrollment:**	DLI_DT
FUNCTIONAL TESTS					
Total distance walked in 2 minutes:	☐ Missing	Number of laps	x 50 ft=_____	+ Partial lap _____ft	=WALK_____Feet walked in 2 min
Grip strength (dominant hand)	☐ Missing	Trial #1 lb	Trial #2 lb	Trial #3 lb	Ave GRIP	Position (1-5) GRIP_POS
Portable Spirometer FEV-1	☐ Missing	Trial #1 L/sec	Trial #2 L/sec	Trial #3 L/sec	Ave in L FEV1_SPIRO	Ave as % predicted FEV1_CALC
Schirmer's	☐ Missing	Right Eye (OD) SCH_R mm Minutes: SCH_R_MIN			Left Eye (OS)) SCH_L mm Minutes: SCH_L_MIN	
Reason why data (specify) is missing or not trustworthy:		MISS1 & MISS1_REAS				
Reason why data (specify) is missing or not trustworthy:		MISS2 & MISS2_REAS				

more are in SC_NOTES

This page same as enrollment v1.1 visit pg 1

Abstraction from Medical Chart
At Study-Related Clinic Visit—Follow Up

Study ID		Initials		Date of clinic visit	
DIAGNOSTIC AND LABORATORY DATA					
Range of motion	❑ Not performed		❑ Report attached		
Blood Pressure	mm/Hg		Weight		❑ Kg ❑ Lb
Full PFT	❑ Not performed		❑ Report attached		
PFT with Bronchodilation?	❑ Yes		❑ No	❑ N/A	
Full Volume Capacity (FVC)	L		%		
FEV-1	L/sec		%		
Single breath DLCO (adjusted)	%				
Total WBC	k/ul		Platelet count		k/ul
% Eosinophils	%		% Neutrophils		%
% Lymphocytes	%				
Total serum bilirubin	mg/dL		ALT		units/L
Alkaline Phosphatase	units/L		Albumin		gm/dL
Creatinine	mg/dL		Glucose		mg/dL

Instructions for lipid panel and urinalysis: Scan interval between study visits. Ok if missing (write -1). For enrollment: first choose up to 2 mo prior, if not, then 1 mo post

Date of lipid panel		Date of urinalysis	
Fasting for lipids?	❑ Yes	❑ No	❑ Unknown
Cholesterol	mg/dL	Triglycerides	mg/dL
LDL	mg/dL	HDL	mg/dL
Urine creatinine/microalbumin	URN mg/g creatinine		

Blood in Urine (Dipstick)	❑ Not done	❑ 0	❑ Tr	❑ 1+	❑ 2+	❑ 3+	❑ 4+
Protein in Urine (Dipstick)	❑ Not done	❑ 0	❑ Tr	❑ 1+	❑ 2+	❑ 3+	❑ 4+

Current Medications' Dose Regimens

List dose regimen of antibiotics, steroids, immunosuppressants & other GVHD therapy that the patient is currently taking. Do not include dosage changes prescribed on today's visit.

Abstraction from Medical Chart
At Study-Related Clinic Visit—Follow Up

INTERVAL DATA (meds, bx, hosp's): applicable for interval between two actual study visits

Last study visit: _____ **This study visit:** _____

Instructions for GVHD Therapy
List: steroids, immunosuppressants, and other GVHD therapy
Please see the Data Entry FAQ for a complete list
If steroid, give max dose

THERAPY GIVEN FOR CHRONIC GVHD

Steroid	Max Dose for Chronic	Other GVHD Therapy	Other GVHD Therapy
1. MAX_STER1	MAX_DOSE1 MAX-FREQ1	1. INT_MED1	6.
2.		2.	7.
3.		3.	8.
Notes:	(also mg-kg)	4.	9.
		5.	10. INT_MED10

MEDS_INTERVAL

(also protocol and none)

Number of **biopsy** samples taken during *interval* between study visits?	BX	
Area of body:	**Date of biopsy**	**Location**
BX_AREA	BX_DT	☐1 At center ☐2 Outside center BX_LOC
BX_AREA2	BX_DT2	☐ At center ☐ Outside center BX_LOC2
		☐ At center ☐ Outside center

Was patient hospitalized during *interval*?	HOSP
# of days in hospital during *interval*	HOSP_DAYS

OR: **Dates of Admission and Discharge from Hospital** *(you can choose between days or dates)*

Admit	Discharge	Admit	Discharge
ADM_1	DIS_1	ADM_3	DIS_3
ADM_2	DIS_2	ADM_4	DIS_4

# of visits with study provider during *interval*	Instructions: oncologist or transplanter of the visit for which you are doing chart review	VISITS_PROV
# of visits with other clinic providers during *interval*	Instructions: oncologists or transplanters only; include center and local MDs	VISITS_OTH

Abstraction from Medical Chart
At Study-Related Clinic Visit—Follow Up

FUNCTIONAL TESTS									
Total distance walked in 2 minutes:	❑ Missing	Number of laps	x 50 ft=_____	+ Partial lap _____ft	=_____Feet walked in 2 min				
Grip strength (dominant hand)	❑ Missing	Trial #1 lb	Trial #2 lb	Trial #3 lb	Ave	Position (1-5)			
Portable Spirometer FEV-1	❑ Missing	Trial #1 L/sec	Trial #2 L/sec	Trial #3 L/sec	Ave in L	Ave as % predicted			
Schirmer's	❑ Missing	Right Eye (OD) mm Minutes:			Left Eye (OS)) mm Minutes:				
Reason why data (specify) is missing or not trustworthy:									
Reason why data (specify) is missing or not trustworthy:									

Same as variables on chart review-visit enrollment v1.1

Chronic GVHD Protocol

Improving outcomes assessment in chronic GVHD

Provider Survey

Enrollment

Instructions:
Please score a symptom only if you know or suspect it be *related to chronic GVHD.* Subjective symptoms are acceptable. For example, joint tightness can be scored based on subjective findings despite the absence of objective limitations.

Please score symptoms present in the *last week.* Even if they may have resolved with treatment in the past week, if they were present recently and may possibly return, please score them.

Date of Visit: _____

Patient: _____

MRN: _____

cGVHD Dx Date: _____

Your Name: _____

SKIN

Do not use Rule of 9s Indicate % of body part affected	*Check ONE area of the body as the sentinel lesion* SL_1	Erythematous rash of any sort	Moveable sclerosis	Non-moveable subcutaneous sclerosis or fasciitis
1. Head/neck/scalp	☐ 1	ESKIN1 %	MSKIN1 %	FSKIN1 %
2. Anterior torso	☐ 2	%	%	%
3. Posterior torso	☐ 3	%	%	%
4. L. upper extremity	☐ 4	%	%	%
5. R. upper extremity	☐ 5	%	%	%
6. L. lower extremity, (incl. L buttock)	☐ 6	%	%	%
7. R. lower extremity, (incl. R buttock)	☐ 7	%	%	%
8. Genitalia ○ ☐ not examined GEN_BSA	☐ 8	ESKIN8 %	MSKIN8 %	FSKIN8 %

Skin sclerotic changes	0	1	2	3	4
	☐ Normal J_SKIN	☐ Thickened with pockets of normal skin	☐ Thickened over majority of skin	☐ Thickened, unable to move	☐ Hidebound, unable to pinch

Skin Score	0	1	2	3
	☐ No Symptoms SC_SKIN	☐ <18% BSA with disease signs but **NO** sclerotic features	☐ 19-50% BSA **OR** involvement with superficial sclerotic features "not hidebound" (able to pinch)	☐ >50% BSA **OR** deep sclerotic features "hidebound" (unable to pinch) **OR** impaired mobility, ulceration or severe pruritus
Fascia	☐ Normal J_FASCIA	☐ Tight with normal areas	☐ Tight	☐ Tight, unable to move

Clinical Skin Features

☐ Ulcer ULCER Location: ULCER_LOC Largest dimension: ULC_SZ1 ULC_SZ2 cm

☐ Maculopapular rash	MPRASH	☐ Keratosis pilaris	KPIL
☐ Lichen planus-like lesions	LICH	☐ Papulosquamous lesions or icthyosis	ICTH
☐ Poikiloderma	POIK	☐ Hair involvement	HAIR
☐ Pruritus	PRUR	☐ Nail involvement	NAIL
☐ Other, specify:	OTHSKIN	☐ Other, specify:	OTHSKIN_SPEC

SKIN

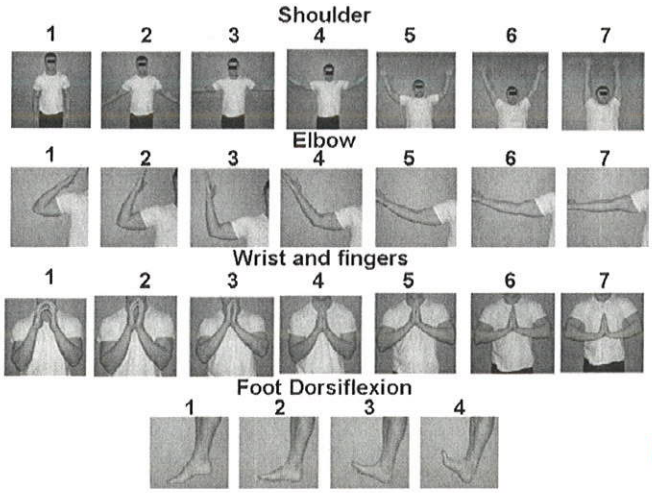
Region	Grade	% Area of Grade	Fraction of Grade 3 or 4 Areas with Erythema (indicate up to what fraction is involved)
1. Head, Neck and Scalp SL-2 ☐1	0 TSS1_0	%	
	1 TSS1_1	%	
	2 TSS1_2	%	TSS1_3A
	3 TSS1_3	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	4 TSS1_4	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	Total =	**100 %**	TSS1_4A
2. Chest ☐2	0	%	
	1	%	
	2	%	
	3	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	4	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	Total =	**100 %**	
3. Abdomen and Genitals ☐3	0	%	
	1	%	
	2	%	
	3	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	4	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	Total =	**100 %**	
4. Back and Buttocks ☐4	0	%	
	1	%	
	2	%	
	3	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	4	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	Total =	**100 %**	
5. Right Arm ☐5	0		
	1		
	2		
	3		☐0 ☐¼ ☐½ ☐¾ ☐1
	4	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	Total =	**100 %**	
6. Right Hand ☐6	0 TSS6_0	%	
	1 TSS6_1	%	
	2 TSS6_2	%	TSS6_3A
	3 TSS6_3	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	4 TSS6_4	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	Total =	**100 %**	TSS6_4A
7. Left Arm ☐7	0	%	
	1	%	
	2	%	
	3	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	4	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	Total =	**100 %**	
8. Left Hand ☐8	0	%	
	1	%	
	2	%	
	3	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	4	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	Total =	**100 %**	
9. Right Leg and Foot ☐9	0	%	
	1	%	
	2	%	
	3	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	4	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	Total =	**100 %**	
10. Left Leg and Foot ☐10	0		
	1		
	2		
	3	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	4	%	☐0 ☐¼ ☐½ ☐¾ ☐1
	Total =	**100 %**	

Check ONE area of the body as the sentinel lesion.

0 = normal skin
1 = discolored [hypopigmentation, hyperpigmentation, alopecia, erythema, maculopapular rash]
2 = lichenoid plaque, or skin thickened (able to move)
3 = skin thickened with limited motion but able to pinch [scleroderma or fasciae involvement]
4 = hidebound skin, unable to move, unable to pinch

ROM & MOUTH

Please circle this person's current ROM for each joint from 1=poor mobility to 7=full mobility below:



ROM_SHR

ROM_ELB

ROM_WRI

ROM_FOOT

		0	1	2	3
Mouth Score		❑ No symptoms SC_MOUTH	❑ Mild symptoms with disease signs but not limiting oral intake significantly	❑ Moderate symptoms with signs with **partial** limitation of oral intake	❑ Severe symptoms with disease signs on examination with **major** limitation of oral intake
Mouth	**Erythema**	❑ None R_MOUTH_E	❑ Mild erythema OR Moderate erythema (<25%)	❑ Moderate (≥25%) OR Severe erythema (<25%)	❑ Severe erythema (≥25%)
	Lichenoid	❑ None R_MOUTH_L	❑ Hyperkeratotic changes (<25%)	❑ Hyperkeratotic changes (25-50%)	❑ Hyperkeratotic changes (>50%)
	Ulcers	❑ None R_MOUTH_U	❑ None	❑ Ulcers involving (≤20%)	❑ Severe ulcerations (>20%)
	Mucoceles (of lower labia and soft palate only)	❑ None R_MOUTH_M	❑ 1-5 mucoceles	❑ 6-10 scattered mucoceles	❑ Over 10 mucoceles
Mouth Pain		❑ No symptoms	❑ Food sensitivity J_MOUTH	❑ Pain requiring narcotics	❑ Unable to eat

GASTROINTESTINAL

GI Tract Score		0	1	2	3
		❑ No symptoms SC_GI	❑ Symptoms such as dysphagia, anorexia, nausea, vomiting, abdominal pain or diarrhea without significant weight loss (<5%)	❑ Symptoms associated with mild to moderate weight loss (5-15%)	❑ Symptoms associated with significant weight loss >15%, requires nutritional supplement for most calorie needs **OR** esophageal dilation
Gastro-intestinal	**Esophagus** • **Dysphagia OR** • **Odynophagia**	❑ No esophageal symptoms R_ESO	❑ Occasional dysphagia or odynophagia with solid food or pills *during the past week*	❑ Intermittent dysphagia or odynophagia with solid food or pills (but not for liquids or soft foods) *during the past week*	❑ Dysphagia or odynophagia for almost all oral intake, *on almost every day of the past week*
	Upper GI • **Early satiety OR** • **Anorexia OR** • **Nausea & vomiting**	❑ No symptoms R_UGI	❑ Mild, occasional symptoms with little reduction in oral intake *during the past week*	❑ Moderate, intermittent symptoms throughout the day, with some reduction in oral intake, *during the past week*	❑ More severe or persistent symptoms throughout the day, with marked reduction in oral intake, *on almost every day of the past week*
	Lower GI • **Diarrhea**	❑ No loose or liquid stools *during the past week* R_LGI	❑ Occasional loose or liquid stools, on some days *during the past week*	❑ Intermittent loose or liquid stools through-out the day, *on almost every day of the past week* **without requiring** intervention to prevent or correct volume depletion	❑ Voluminous diarrhea *on almost every day of the past week* **requiring** intervention to prevent or correct volume depletion

OTHER ORGANS

	0	1	2	3
Eye Score	❑ No symptoms SC_EYE	❑ Mild dry eye symptoms not affecting ADL (requiring eye drops <3x per day) **OR** asymptomatic signs of kerato-conjunctivitis sicca	❑ Moderate dry eye symptoms partially affecting ADL (requiring eye drops >3x per day or punctual plugs) **WITHOUT** vision impairment	❑ Severe dry eye symptoms significantly affecting ADL (special eyewear to relieve pain) **OR** unable to work because of ocular symptoms **OR** loss of vision caused by kerato-conjunctivitis sicca
Joints and Fascia Score	❑ No symptoms SC_JOINT	❑ Mild tightness of arms or legs, normal or mild decreased range of motion (ROM) **AND** not affecting ADL	❑ Tightness of arms or legs **OR** joint contractures, erythema thought due to fasciitis, moderate decrease ROM **AND** mild to moderate limitation of ADL	❑ Contracture WITH significant decrease of ROM **AND** significant limitation of ADL (unable to tie shoes, button shirts, dress self etc.)
Genital Tract Score GYN_EXAM **(score even if no GYN exam, required for men too)** 1=not performed ❑ **No GYN Exam**	❑ No symptoms SC_GENITAL	❑ Symptomatic with mild distinct signs on exam AND no effect on coitus and minimal discomfort with GYN exam	❑ Symptomatic with distinct signs on exam AND with mild dyspareunia or discomfort with GYN exam	❑ Symptomatic WITH advanced signs (stricture, labia agglutination or severe ulceration) AND severe pain with coitus or inability to insert vaginal spectrum
Lung Score	❑ No symptoms SC_LUNG	❑ Mild symptoms (shortness of breath after climbing one flight of steps)	❑ Moderate symptoms (shortness of breath after walking on flat ground)	❑ Severe symptoms (shortness of breath at rest; requiring O_2)
Other Organ Score *Specify:*	❑ No effect on ADL SC_OTH1 SC_OTH1_SPEC	❑ Mild effect on ADL	❑ Moderate effect on ADL	❑ Severe effect on ADL
Other Organ Score *Specify:*	❑ No effect on ADL SC_OTH2 SC_OTH2_SPEC	❑ Mild effect on ADL	❑ Moderate effect on ADL	❑ Severe effect on ADL

OVERALL STATUS

Please rate the severity of this person's chronic GVHD				
on this scale →	❑ None (0)	❑ Mild (1)	❑ Moderate (2)	❑ Severe (3)
and on this scale → *(circle one)*	MD_SEV_mmS cGVHD symptoms are not at all severe ⟷ cGVHD symptoms are most severe possible 0 1 2 3 4 5 6 7 8 9 10 MD_SEV10			

Reasons for changing therapeutic regimen (check all that apply) prefix = RXCHG_

❑ Not applicable, no changes made	NA
❑ Adjust levels of medications	LEVEL
❑ Enroll on clinical trial	TRIAL
❑ Worsening of symptoms	WORSE
❑ No improvement in symptoms	NOIMPROV
❑ Toxicity	TOX
❑ New symptoms	NEWSX
❑ Improvement in symptoms	IMPROV
❑ Disease relapse	REL
❑ Stable	STABLE

Sentinel Organ
Response in which organ system will guide your treatment decisions (If more than one, please rank)

❑ Skin	SO_SKIN
❑ Joints	SO_JOINT
❑ Fascia	SO_FASCIA
❑ Lung	SO_LUNG
❑ Urogenital	SO_GENITAL
❑ Liver	SO_LIVER
❑ Mouth	SO_MOUTH
❑ Esophagus	SO_ESO
❑ Lower GI	SO_LGI
❑ Other specify:	SO_OTH SO_OTHSPEC

Does this person *currently* have: GVHD_CURRENT

- ❑ Late acute GVHD (1)
- ❑ Overlap acute and chronic GVHD (2)
- ❑ Classic chronic GVHD (3)
- ❑ No GVHD (0)

Infection	0	1	2	3	4
	❑ None J_INF	❑ Mild, topical or no therapy required	❑ Moderate, localized, requiring oral treatment For 2-4:	❑ Severe, systemic infection requiring IV anti-infective, mold-active oral antifungal or hospitalization	❑ Life-threatening infection
		❑ Pending lab report (1)	❑ Unidentified organism (2) J_INF_ID	❑ Identified organism, specify (3): J_INF_SPEC	

OVERALL STATUS

EDEMA

Peripheral Edema?	❑ None (0)	❑ Tr (9)	❑ 1+	❑ 2+	❑ 3+	❑ 4+

Other indicators, clinical manifestations or severe complications related to chronic GVHD					
	Never (0)	Past, not now (1)	Mild (2)	Moderate (3)	Severe (4)
CM 1. Pleural Effusion(s)	❑	❑	❑	❑	❑
2. Bronchiolitis obliterans	❑	❑	❑	❑	❑
3. Bronchiolitis obliterans organizing pneumonia	❑	❑	❑	❑	❑
4. Nephrotic syndrome	❑	❑	❑	❑	❑
5. Malabsorption	❑	❑	❑	❑	❑
6. Esophageal stricture or web	❑	❑	❑	❑	❑
7. Ascites (serositis)	❑	❑	❑	❑	❑
8. Myasthenia Gravis	❑	❑	❑	❑	❑
9. Peripheral Neuropathy	❑	❑	❑	❑	❑
10. Polymyositis	❑	❑	❑	❑	❑
11. Pericardial Effusion	❑	❑	❑	❑	❑
12. Cardiomyopathy	❑	❑	❑	❑	❑
13. Cardiac conduction defects	❑	❑	❑	❑	❑
CM 14. Coronary artery involvement	❑	❑	❑	❑	❑
15. Other, please specify: CM15_OTH CM15_OTHSPEC	❑	❑	❑	❑	❑
16. Other, please specify: CM16_OTH CM16_OTHSPEC	❑	❑	❑	❑	❑
17. Other, please specify: CM17_OTH CM17_OTHSPEC	❑	❑	❑	❑	❑

For office use only:

Study ID	*Initials (First, Last)*	*Date completed:* COMPL_DT	*Date received:* REC_DT
Person completing form: FIRST_NAME LAST_NAME		*Their degree:* DEGREE	
Timepoint: ↓ in MD_ID codes		*Date entered:* ↓ in MD_ID codes	

v3.2

Chronic GVHD Protocol

Improving outcomes assessment in chronic GVHD

Provider Survey

Follow-up

Instructions:
Please score a symptom only if you know or suspect it be *related to chronic GVHD.* Subjective symptoms are acceptable. For example, joint tightness can be scored based on subjective findings despite the absence of objective limitations.

Please score symptoms present in the *last week.* Even if they may have resolved with treatment in the past week, if they were present recently and may possibly return, please score them.

Date of Visit: _____

Patient: _____

MRN: _____

cGVHD Dx Date: _____

Your Name: _____

ONLY SHOWING DIFFERENCES FROM ENROLLMENT v3.2

FOLLOW UP VERSION

SKIN

Do not use Rule of 9s *Indicate % of body part affected* no SL-1		Erythematous rash of any sort	Moveable sclerosis	Non-moveable subcutaneous sclerosis or fasciitis
1. **Head/neck/scalp**		%	%	%
2. **Anterior torso**		%	%	%
3. **Posterior torso**		%	%	%
4. **L. upper extremity**		%	%	%
5. **R. upper extremity**		%	%	%
6. **L. lower extremity,** (incl. L buttock)		%	%	%
7. **R. lower extremity,** (incl. R buttock)		%	%	%
8. **Genitalia**	❑ not examined	%	%	%

	0	1	2	3	4
Skin sclerotic changes	❑ Normal	❑ Thickened with pockets of normal skin	❑ Thickened over majority of skin	❑ Thickened, unable to move	❑ Hidebound, unable to pinch

	0	1	2	3
Skin Score	❑ No Symptoms	❑ <18% BSA with disease signs but **NO** sclerotic features	❑ 19-50% BSA **OR** involvement with superficial sclerotic features "not hidebound" (able to pinch)	❑ >50% BSA **OR** deep sclerotic features "hidebound" (unable to pinch) **OR** impaired mobility, ulceration or severe pruritus
Fascia	❑ Normal	❑ Tight with normal areas	❑ Tight	❑ Tight, unable to move

Clinical Skin Features

❑ Ulcer Location: _____ Largest dimension: _____ cm

❑ Maculopapular rash	❑ Keratosis pilaris
❑ Lichen planus-like lesions	❑ Papulosquamous lesions or icthyosis
❑ Poikiloderma	❑ Hair involvement
❑ Pruritus	❑ Nail involvement
❑ Other, specify:	❑ Other, specify:

FOLLOW UP VERSION

SKIN

Region	Grade	% Area of Grade	Fraction of Grade 3 or 4 Areas with Erythema (indicate up to what fraction is involved)	Region	Grade	% Area of Grade	Fraction of Grade 3 or 4 Areas with Erythema (indicate up to what fraction is involved)
no SL_2							
1. Head, Neck and Scalp	0	%		6. Right Hand	0	%	
	1	%			1	%	
	2	%			2	%	
	3	%	❑0 ❑¼ ❑½ ❑¾ ❑1		3	%	❑0 ❑¼ ❑½ ❑¾ ❑1
	4	%	❑0 ❑¼ ❑½ ❑¾ ❑1		4	%	❑0 ❑¼ ❑½ ❑¾ ❑1
	Total =	**100 %**			**Total =**	**100 %**	
2. Chest	0	%		7. Left Arm	0	%	
	1	%			1	%	
	2	%			2	%	
	3	%	❑0 ❑¼ ❑½ ❑¾ ❑1		3	%	❑0 ❑¼ ❑½ ❑¾ ❑1
	4	%	❑0 ❑¼ ❑½ ❑¾ ❑1		4	%	❑0 ❑¼ ❑½ ❑¾ ❑1
	Total =	**100 %**			**Total =**	**100 %**	
3. Abdomen and Genitals	0	%		8. Left Hand	0	%	
	1	%			1	%	
	2	%			2	%	
	3	%	❑0 ❑¼ ❑½ ❑¾ ❑1		3	%	❑0 ❑¼ ❑½ ❑¾ ❑1
	4	%	❑0 ❑¼ ❑½ ❑¾ ❑1		4	%	❑0 ❑¼ ❑½ ❑¾ ❑1
	Total =	**100 %**			**Total =**	**100 %**	
4. Back and Buttocks	0	%		9. Right Leg and Foot	0	%	
	1	%			1	%	
	2	%			2	%	
	3	%	❑0 ❑¼ ❑½ ❑¾ ❑1		3	%	❑0 ❑¼ ❑½ ❑¾ ❑1
	4	%	❑0 ❑¼ ❑½ ❑¾ ❑1		4	%	❑0 ❑¼ ❑½ ❑¾ ❑1
	Total =	**100 %**			**Total =**	**100 %**	
5. Right Arm	0			10. Left Leg and Foot	0		
	1				1		
	2				2		
	3		❑0 ❑¼ ❑½ ❑¾ ❑1		3	%	❑0 ❑¼ ❑½ ❑¾ ❑1
	4	%	❑0 ❑¼ ❑½ ❑¾ ❑1		4	%	❑0 ❑¼ ❑½ ❑¾ ❑1
	Total =	**100 %**			**Total =**	**100 %**	

0 = normal skin
1 = discolored [hypopigmentation, hyperpigmentation, alopecia, erythema, maculopapular rash]
2 = lichenoid plaque, or skin thickened (able to move)
3 = skin thickened with limited motion but able to pinch [scleroderma or fasciae involvement]
4 = hidebound skin, unable to move, unable to pinch

FOLLOW UP VERSION

OVERALL STATUS

Please rate the severity of this person's chronic GVHD	
on this scale →	❑ None (0) ❑ Mild (1) ❑ Moderate (2) ❑ Severe (3) MD_SEV_mms
and on this scale → (circle one)	cGVHD symptoms are not at all severe ⟷ cGVHD symptoms are most severe possible 0 1 2 3 4 5 6 7 8 9 10 MD_SEV 10

* **Current GVHD Status**	❑ Complete response (1) MD_STATUS	❑ Partial response (2)	❑ Unchanged (3)	❑ Progressive (4)

Reasons for changing therapeutic regimen (Check all that apply) prefix = RXCHG_	
❑ Not applicable, no changes made NA	❑ Toxicity TOX
❑ Adjust levels of medications LEVEL	❑ New symptoms NEWSX
❑ Enroll on clinical trial TRIAL	❑ Improvement in symptoms IMPROV
❑ Worsening of symptoms WORSE	❑ Disease relapse REL
❑ No improvement in symptoms NOIMPROV	❑ Stable STABLE

Does this person *currently* have: GVHD_CURRENT	❑ Late acute GVHD (1) ❑ Overlap acute and chronic GVHD (2) ❑ Classic chronic GVHD (3) ❑ No GVHD (0)

FOLLOW UP VERSION

OVERALL STATUS

Since the last study visit six months ago on _____, how would you say this patient's chronic GVHD has changed?

prefix = CHG_

	Not involved (0)	Resolved (1)	Very much better (2)	Moderately better (3)	A little better (4)	About the same (5)	A little worse (6)	Moderately worse (7)	Very much worse (8)
Mouth MOUTH	❑	❑	❑	❑	❑	❑	❑	❑	❑
Skin SKIN	❑	❑	❑	❑	❑	❑	❑	❑	❑
Eyes EYE	❑	❑	❑	❑	❑	❑	❑	❑	❑
Joints JOINT	❑	❑	❑	❑	❑	❑	❑	❑	❑
Chronic GVHD Overall		GVHD ❑	❑	❑	❑	❑	❑	❑	❑

*

What are your reasons for how you rated "chronic GVHD overall"? *Write in* ➔ (For example, has an organ or symptom improved or worsened?)	CHG_REASON

Infection J_INFX	0	1	2	3	4
	❑ None	❑ Mild, topical or no therapy required	❑ Moderate, localized, requiring oral treatment For 2-4:	❑ Severe, systemic infection requiring IV anti-infective, mold-active oral antifungal or hospitalization	❑ Life-threatening infection
		❑ Pending lab report (1)	❑ Unidentified organism (2)	❑ Identified organism, specify (3):	

Peripheral Edema? EDEMA	❑ None (0)	❑ Tr (9)	❑ 1+	❑ 2+	❑ 3+	❑ 4+

FOLLOW UP VERSION

OVERALL STATUS

Other indicators, clinical manifestations or severe complications related to chronic GVHD					
	Never (0)	Past, not now (1)	Mild (2)	Moderate (3)	Severe (4)
1. Pleural Effusion(s)	❑	❑	❑	❑	❑
2. Bronchiolitis obliterans	❑	❑	❑	❑	❑
3. Bronchiolitis obliterans organizing pneumonia	❑	❑	❑	❑	❑
4. Nephrotic syndrome	❑	❑	❑	❑	❑
5. Malabsorption	❑	❑	❑	❑	❑
6. Esophageal stricture or web	❑	❑	❑	❑	❑
7. Ascites (serositis)	❑	❑	❑	❑	❑
8. Myasthenia Gravis	❑	❑	❑	❑	❑
9. Peripheral Neuropathy	❑	❑	❑	❑	❑
10. Polymyositis	❑	❑	❑	❑	❑
11. Pericardial Effusion	❑	❑	❑	❑	❑
12. Cardiomyopathy	❑	❑	❑	❑	❑
13. Cardiac conduction defects	❑	❑	❑	❑	❑
14. Coronary artery involvement	❑	❑	❑	❑	❑
15. Other, please specify: _____	❑	❑	❑	❑	❑
16. Other, please specify: _____	❑	❑	❑	❑	❑
17. Other, please specify: _____	❑	❑	❑	❑	❑

For office use only:

Study ID	*Initials (First, Last)*	*Date completed:*	*Date received:*
Person completing form:		*Their degree:*	
Timepoint:	*v3.2*	*Date entered:*	

Chronic GVHD Patient Survey

ENROLLMENT

INSTRUCTIONS

This survey will provide us with important information about your health.

All your answers will be kept strictly confidential and will not be included in your medical record. The information that you provide will be combined with that of many other transplant patients before analysis.

Please read each question carefully. Circle or check off the answer that best describes how you feel.

While we ask that you answer each question, you are free to *not* answer any question that makes you feel uncomfortable. If none of the answers provided seems exactly right, choose the one that comes closest to being right for you. Some of the questions may seem the same. However, it is important that we ask about certain aspects of your health in different ways in order to fully understand how you are feeling.

When you have completed this survey, please give it back to the study coordinator or mail it back to us using the enclosed self-addressed, stamped envelope.

We greatly appreciate your participation.

Your name: _____ **Date:** COMPL_DT

Section 1: Your Chronic Graft vs. Host Disease (GVHD) Symptoms

Please circle the number that shows how severe your symptoms have been **in the last week**:

	Not Present									As Bad As You Can Imagine
PSR 1. Your chronic GVHD symptoms **overall**?	0	1	2	3	4	5	6	7	8	9	10
2. Your **skin itching** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
3. Your **mouth dryness** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
4. Your **mouth pain** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
5. Your **mouth sensitivity** at its WORST?	0	1	2	3	4	5	6	7	8	9	10
6. Your **eye** problem at its WORST?	0	1	2	3	4	5	6	7	8	9	10

7. What is your main complaint with regard to your eyes?

   (Write in): _____

8. ***Vulvovaginal Symptoms (females only):*** Do you have any burning, pain or discomfort in the area of your vagina, vulva or labia? - **OR -** Do you have any discomfort or pain with sexual intercourse?
   1-☐ Yes 0-☐ No -2-☐ Not applicable

9. ***(Male and female)*** Overall, how would you rate the severity of your chronic graft versus host disease?
   0-☐ None
   1-☐ Mild
   2-☐ Moderate
   3-☐ Severe

PSR 10. Do you think your chronic GVHD symptoms are in good enough control to decrease your immunosuppressive medications?
   0-☐ No
   1-☐ Yes
   -2-☐ Not applicable

2 Don't know

FOLLOW UP VERSION

Compared to your last study visit six months ago on _____, how would you rate your following GVHD symptoms now?

		Not involved with GVHD	Compl-etely gone	Very much better	Moder-ately better	A little better	About the same	A little worse	Moder-ately worse	Very much worse
PSR 11.	**GVHD symptoms overall**	--	1	2	3	4	5	6	7	8
12.	**Mouth**	0	1	2	3	4	5	6	7	8
13.	**Skin**	0	1	2	3	4	5	6	7	8
14.	**Eye**	0	1	2	3	4	5	6	7	8
15.	**Joints**	0	1	2	3	4	5	6	7	8

PSR 16. What are your reasons for saying your chronic GVHD is better or worse overall? (Is there a symptom of particular concern to you that has changed?)

(Write in)

_____

_____

_____

_____

_____

_____

inserted between pg 2 & 3 of baseline version

Please continue to next page ☞

Section 2

By circling one (1) number per line, please indicate how much you have been bothered by the following problems in the past month:

SKIN:	Not at all	Slightly	Moderately	Quite a bit	Extremely
SX 1. Abnormal skin color.....	0	1	2	3	4
2. Rashes.....	0	1	2	3	4
3. Thickened skin.....	0	1	2	3	4
4. Sores on skin.....	0	1	2	3	4
5. Itchy skin.....	0	1	2	3	4

EYES AND MOUTH:	Not at all	Slightly	Moderately	Quite a bit	Extremely
6. Dry eyes.....	0	1	2	3	4
7. Need to use eye drops frequently..	0	1	2	3	4
8. Difficulty seeing clearly.....	0	1	2	3	4
9. Need to avoid certain foods due to mouth pain.....	0	1	2	3	4
10. Ulcers in mouth.....	0	1	2	3	4
11. Receiving nutrition from an intravenous line or feeding tube....	0	1	2	3	4

BREATHING:	Not at all	Slightly	Moderately	Quite a bit	Extremely
12. Frequent cough.....	0	1	2	3	4
13. Colored sputum.....	0	1	2	3	4
14. Shortness of breath with exercise..	0	1	2	3	4
15. Shortness of breath at rest.....	0	1	2	3	4
SX 16. Need to use oxygen.....	0	1	2	3	4

EATING AND DIGESTION:	Not at all	Slightly	Moderately	Quite a bit	Extremely
17. Difficulty swallowing solid foods....	0	1	2	3	4
18. Difficulty swallowing liquids.....	0	1	2	3	4
19. Vomiting.....	0	1	2	3	4
20. Weight loss.....	0	1	2	3	4

MUSCLES AND JOINTS:	Not at all	Slightly	Moderately	Quite a bit	Extremely
21. Joint and muscle aches.....	0	1	2	3	4
22. Limited joint movement.....	0	1	2	3	4
23. Muscle cramps.....	0	1	2	3	4
24. Weak muscles.....	0	1	2	3	4

ENERGY:	Not at all	Slightly	Moderately	Quite a bit	Extremely
25. Loss of energy.....	0	1	2	3	4
26. Need to sleep more/take naps.....	0	1	2	3	4
27. Fevers.....	0	1	2	3	4

MENTAL AND EMOTIONAL:	Not at all	Slightly	Moderately	Quite a bit	Extremely
28. Depression.....	0	1	2	3	4
29. Anxiety.....	0	1	2	3	4
30. Difficulty sleeping.....	0	1	2	3	4

Section 3

new codes for v3.0

Have you experienced any of the following during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time
OD 1. Eyes that are sensitive to light?	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Have problems with your eyes limited you in performing any of the following during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	Not applicable
6. Reading?	4	3	2	1	0	N/A (-2)
7. Driving at night?	4	3	2	1	0	N/A (-2)
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A (-2)
9. Watching TV?	4	3	2	1	0	N/A (-2)

Have your eyes felt uncomfortable in any of the following situations during the last week?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	Not applicable
10. Windy conditions?	4	3	2	1	0	N/A (-2)
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A (-2)
OD 12. Areas that are air conditioned?	4	3	2	1	0	N/A (-2)

Section 4: Quality of Your Life After Your Transplant

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days:

PHYSICAL WELL-BEING:	Not at all	A little bit	Some -what	Quite a bit	Very much
1. I have a lack of energy	0	1	2	3	4
2. I have nausea	0	1	2	3	4
3. Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
4. I have pain	0	1	2	3	4
5. I am bothered by side effects of treatment	0	1	2	3	4
6. I feel ill	0	1	2	3	4
7. I am forced to spend time in bed	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days:

SOCIAL/FAMILY WELL-BEING:	Not at all	A little bit	Some-what	Quite a bit	Very much
8. I feel close to my friends	0	1	2	3	4
9. I get emotional support from my family	0	1	2	3	4
10. I get support from my friends	0	1	2	3	4
11. My family has accepted my illness	0	1	2	3	4
12. I am satisfied with family communication about my illness	0	1	2	3	4
13. I feel close to my partner (or the person who is my main support)	0	1	2	3	4

Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box and go to the next section. ☐ -3

14. I am satisfied with my sex life	0	1	2	3	4

EMOTIONAL WELL-BEING:	Not at all	A little bit	Some-what	Quite a bit	Very much
15. I feel sad	0	1	2	3	4
16. I am satisfied with how I am coping with my illness	0	1	2	3	4
17. I am losing hope in the fight against my illness	0	1	2	3	4
18. I feel nervous	0	1	2	3	4
19. I worry about dying	0	1	2	3	4
20. I worry that my condition will get worse	0	1	2	3	4

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

FUNCTIONAL WELL-BEING:		Not at all	A little bit	Some-what	Quite a bit	Very much
21.	I am able to work (include work at home)	0	1	2	3	4
22.	My work (include work at home) is fulfilling.....	0	1	2	3	4
23.	I am able to enjoy life	0	1	2	3	4
24.	I have accepted my illness	0	1	2	3	4
25.	I am sleeping well.....	0	1	2	3	4
26.	I am enjoying the things I usually do for fun.....	0	1	2	3	4
27.	I am content with the quality of my life right now.....	0	1	2	3	4

ADDITIONAL CONCERNS:		Not at all	A little bit	Some-what	Quite a bit	Very much
28.	I am concerned about keeping my job (include work at home).....	0	1	2	3	4
29.	I feel distant from other people.....	0	1	2	3	4
30.	I worry that the transplant will not work	0	1	2	3	4
31.	The effects of treatment are worse than I had imagined.....	0	1	2	3	4
32.	I have a good appetite.....	0	1	2	3	4
33.	I like the appearance of my body	0	1	2	3	4
34.	I am able to get around by myself.....	0	1	2	3	4
35.	I get tired easily	0	1	2	3	4
36.	I am interested in sex.....	0	1	2	3	4
37.	I have confidence in my nurse(s)	0	1	2	3	4

Section 5: Your Health and Well-Being

This section asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Please answer every question. If you are unsure about how to answer a question, please give the answer that seems closest to how you feel.

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

KPS 1. Which statement describes how you feel most of the time? (please check one)

- ☐ 1. Normal, no difficulties with daily activities
- ☐ 2. Able to carry on normal activities, minor problems
- ☐ 3. Normal activity with effort
- ☐ 4. Able to care for self, but unable to carry on normal activity or active work
- ☐ 5. Require occasional assistance, but able to care for most of needs
- ☐ 6. Require considerable assistance and frequent medical care
- ☐ 7. Disabled, require special care and assistance
- ☐ 8. Severely disabled, hospitalized
- ☐ 9. Very sick, hospitalized

SF 2. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
☐1	☐2	☐3	☐4	☐5

SF 3. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
▼	▼	▼	▼	▼
☐1	☐2	☐3	☐4	☐5

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
SF 4. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
5. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
6. Lifting or carrying groceries	1	2	3
7. Climbing several flights of stairs	1	2	3
8. Climbing one flight of stairs	1	2	3
9. Bending, kneeling, or stooping	1	2	3
10. Walking more than a mile	1	2	3
11. Walking several hundred yards	1	2	3
12. Walking one hundred yards	1	2	3
SF 13. Bathing or dressing yourself	1	2	3

new codes for v3.0

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
SF 14. Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
15. Accomplished less than you would like	1	2	3	4	5
16. Were limited in the kind of work or other activities	1	2	3	4	5
17. Had difficulty performing the work or other activities (for example, it took extra effort)	1	2	3	4	5

During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
18. Cut down on the amount of time you spent on work or other activities	1	2	3	4	5
19. Accomplished less than you would like	1	2	3	4	5
SF 20. Did work or other activities less carefully than usual	1	2	3	4	5

new codes for v3.0

SF 21. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐1	☐2	☐3	☐4	☐5

SF 22. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very Severe
☐1	☐2	☐3	☐4	☐5	☐6

SF 23. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐1	☐2	☐3	☐4	☐5

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
SF	24. Did you feel full of life?	1	2	3	4	5
	25. Have you been very nervous?	1	2	3	4	5
	26. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
	27. Have you felt calm and peaceful?	1	2	3	4	5
	28. Did you have a lot of energy?	1	2	3	4	5
	29. Have you felt downhearted and depressed?	1	2	3	4	5
	30. Did you feel worn out?	1	2	3	4	5
	31. Have you been happy?	1	2	3	4	5
SF	32. Did you feel tired?	1	2	3	4	5

new codes for v3.0

SF 33. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐1	☐2	☐3	☐4	☐5

How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
SF 34. I seem to get sick a little easier than other people	1	2	3	4	5
35. I am as healthy as anybody I know	1	2	3	4	5
36. I expect my health to get worse	1	2	3	4	5
SF 37. My health is excellent	1	2	3	4	5

Section 6: Your Activity Level

Please check each activity according to these directions:

Check Column 1 ("Still Doing This Activity") if you completed the activity unassisted the last time you had the need or opportunity to do so.

Check Column 2 ("Have Stopped Doing This Activity") if you have engaged in the activity in the past, but you probably would not perform the activity today even if the opportunity should arise.

Check Column 3 ("Never Did This Activity") if you have never engaged in the specific activity.

	Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
1. Getting in and out of chairs or bed (without assistance)			
2. Listening to the radio			
3. Reading books, magazines or newspapers			
4. Writing (letters, notes)			
5. Working at a desk or table			
6. Standing (for more than one minute)			
7. Standing (for more than five minutes)			
8. Dressing or undressing (without assistance)			
9. Getting clothes from drawers or closets			
10. Getting in or out of a car (without assistance)			
11. Dining at a restaurant			
12. Playing cards/table games			
13. Taking a bath (no assistance needed)			
14. Putting on shoes, stockings or socks (no assistance needed)			
15. Attending a movie, play, church event or sports activity			
16. Walking 30 yards (27 meters)			

	Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
H 17. Walking 30 yards (non-stop)			
18. Dressing/undressing (no rest or break needed)			
19. Using public transportation or driving a car (100 miles or less)			
20. Using public transportation or driving a car (99 miles or more)			
21. Cooking your own meals			
22. Washing or drying dishes			
23. Putting groceries on shelves			
24. Ironing or folding clothes			
25. Dusting/polishing furniture or polishing cars			
26. Showering			
27. Climbing six steps			
28. Climbing six steps (non-stop)			
29. Climbing nine steps			
30. Climbing 12 steps			
31. Walking ½ block on level ground			
32. Walking ½ block on level ground (non-stop)			
33. Making a bed (not changing sheets)			
34. Cleaning windows			
35. Kneeling, squatting to do light work			
36. Carrying a light load of groceries			
H 37. Climbing nine steps (non-stop)			

	Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
38. Climbing 12 steps (non-stop)			
39. Walking ½ block uphill			
40. Walking ½ block uphill (non-stop)			
41. Shopping (by yourself)			
42. Washing clothes (by yourself)			
43. Walking one block on level ground			
44. Walking two blocks on level ground			
45. Walking one block on level ground (non-stop)			
46. Walking two blocks on level ground (non-stop)			
47. Scrubbing (floors, walls or cars)			
48. Making beds (changing sheets)			
49. Sweeping			
50. Sweeping (five minutes non-stop)			
51. Carrying a large suitcase or bowling (one line)			
52. Vacuuming carpets			
53. Vacuuming carpets (five minutes non-stop)			
54. Painting (interior/exterior)			
55. Walking six blocks on level ground			
56. Walking six blocks on level ground (non-stop)			
57. Carrying out the garbage			
58. Carrying a heavy load of groceries			

	Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
59. Climbing 24 steps			
60. Climbing 36 steps			
61. Climbing 24 steps (non-stop)			
62. Climbing 36 steps (non-stop)			
63. Walking one mile			
64. Walking one mile (non-stop)			
65. Running 110 yards (100 meters) or playing softball/baseball			
66. Dancing (social)			
67. Doing calisthenics or aerobic dancing (5 minutes non-stop)			
68. Mowing the lawn (power mower, but not a riding mower)			
69. Walking two miles			
70. Walking two miles (non-stop)			
71. Climbing 50 steps			
72. Shoveling, digging or spading			
73. Shoveling, digging or spading (five minutes non-stop)			
74. Climbing 50 steps (non-stop)			
75. Walking three miles or golfing 18 holes without a riding cart			
76. Walking three miles (non-stop)			
77. Swimming 25 yards			
78. Swimming 25 yards (non-stop)			

	Still Doing This Activity (1)	Have Stopped Doing This Activity (2)	Never Did This Activity (3)
79. Bicycling one mile			
80. Bicycling two miles			
81. Bicycling one mile (non-stop)			
82. Bicycling two miles (non-stop)			
83. Running or jogging ¼ mile			
84. Running or jogging ½ mile			
85. Playing tennis or racquetball			
86. Playing basketball (game play)			
87. Running or jogging ¼ mile (non-stop)			
88. Running or jogging ½ mile (non-stop)			
89. Running or jogging one mile			
90. Running or jogging two miles			
91. Running or jogging three miles			
92. Running or jogging one mile in 12 minutes or less			
93. Running or jogging two miles in 20 minutes or less			
94. Running or jogging three miles in 30 minutes or less			

Section 7: About Yourself

1. What is your current work status? (circle **all** that apply)

SD_WORK1
SD_WORK2
SD_WORK3
SD_WORK4
SD_WORK5
SD_WORK6
SD_WORK7
SD_WORK8
SD_WORK9
SD_WORK10
SD_WORK12

In school full time 1
In school part time 2
Working full time 3
Working part time 4
Homemaker 5
Retired 6
On medical leave from work 7
Disabled, unable to work 8
Unemployed, looking for work 9
Unemployed, not looking for work 10
Other, specify _____ 12

SD_WORK_OTH

2. Do you consider yourself to be Latino(a) or Hispanic?

SD_ETH

No, not Latino/Hispanic 1
Yes, Latino/Hispanic 2

3. How would you best describe your race? (Circle **all** that apply):

SD_RACE1
SD_RACE2
SD_RACE3
SD_RACE4
SD_RACE5
SD_RACE6

Black 1
American Indian/Alaskan Native 2
Asian 3
Hawaiian Native/Pacific Islander 4
White 5
Other, specify _____ 6

SD_RACE_OTH

4. What is your gender?

SD_GEN

Male 1
Female 2

5. How old are you? _____ years

SD_AGE

6. How much did you weigh before your transplant?
Please be sure to indicate if in pounds (lbs) or kilograms (kg).

Kg=1
lb=2

SD_WT
SD_WT_UNIT

7. What is your marital status?

SD_MARITAL

Married/Living with partner 1
Single, Never married 2
Divorced, Separated 3
Widowed 4
Other, specify SD_MAR_OTH 5

8. What is the highest grade of school you have completed?

SD_EDUC

Grade school 1
Some high school 2
High school graduate 3
Some college 4
College graduate 5
Post graduate degree 6

9. What was your approximate annual family income in the year before you had your transplant?

SD_INCOME

Under $15,000 1
$15,000 - $24,999 2
$25,000 - $49,999 3
$50,000 – $74,999 4
$75,000 - $99,999 5
$100,000 or above 6

10. Help us stay in contact with you if you move! We will need to stay in touch with you over the next several years, so please provide the name, address and phone number of a person **NOT LIVING WITH YOU** who will always know where you are, and who would be willing to let us contact them should we have trouble reaching you (for example, a parent, child or good friend who *lives separately from you*). Please be sure that they give permission for us to contact them for this purpose.

not in DB

Name: _____

Address: _____

_____

Phone: _____

Relationship to you: _____

11. Would you like us to contact you about research studies related to chronic GVHD in the future? We would tell you more about the study at the time and you would be free to say yes or no.

1 ❑ Yes please contact me

2 ❑ No thanks

SD_FUTURE

Thank you for participating in this study

Please remember that someone is available to speak with you at any time, if you wish.
Dr. <<Site PI>> may be reached by calling <<Site PI phone>>. (S)he will be able to answer any questions about the study or refer you to other support staff as needed.

Please use the space below for any other comments.

_____

_____

_____

_____

_____

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_____

For office use only:

Study ID	*Initials (First, Last)*	*Date completed:*	*Date received:*
Timepoint: *V3.0*		*Date entered:*	

FOLLOW UP VERSION

Section 7: About Yourself

1. What is your current work status? (circle **all** that apply)

In school full time.....1
In school part time.....2
Working full time.....3
Working part time.....4
Homemaker.....5
Retired.....6
On medical leave from work.....7
Disabled, unable to work.....8
Unemployed, looking for work.....9
Unemployed, not looking for work... 10
Other, specify..... 12

Thank you for participating in this study

Please remember that someone is available to speak with you at any time, if you wish. Dr. <<Site PI>> may be reached by calling <<Site PI phone>>. (S)he will be able to answer any questions about the study or refer you to other support staff as needed.

Please use the space below for any other comments.

_____

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For office use only:

Study ID	*Initials (First, Last)*	*Date completed:*	*Date received:*
Timepoint: *V3.0*		*Date entered:*	