

**Blood and Marrow Transplant Clinical
Trials Network**

Follow Up/Chronic GVHD Form (FGV)

Web Version: 1.0; 2.03; 08-15-17

Segment (PROTSEG): A

Visit Number (VISNO):

1. Start of assessment period:(DTPRVAST) (mm/dd/yyyy)

2. End of assessment period:(DTASSESS) (mm/dd/yyyy)

Acute GVHD

3. Maximum overall grade of acute GVHD during this assessment period:(FGRAGVH)

0 - No Symptoms of Acute GVHD
1 - I
2 - II
3 - III
4 - IV

4. Did new clinical signs and/or symptoms of acute GVHD develop during this assessment period?(FGAGVDVL) 1 - Yes 2 - No

Only report new clinical signs and/or symptoms of acute GVHD that developed during the assessment period at the top of the form.

5. Date of diagnosis of acute GVHD:(FGAGDGD) (mm/dd/yyyy)

If the date is out of range because the diagnosis occurred before this assessment period, question 4 should be answered '2-No'.

Record the highest severity for the following organ systems at the time of maximum overall grade of acute GVHD.

6. Skin abnormalities:(FGASKNAB)

0 - No Rash
1 - Maculopapular Rash, <25% of Body Surface
2 - Maculopapular Rash, 25-50% of Body Surface
3 - Generalized Erythroderma
4 - Generalized Erythroderma with Bullus Formation and Desquamation

7. Upper GI abnormalities:(FGAUGIAB)

0 - No Protracted Nausea and Vomiting
1 - Persistent Nausea, Vomiting or Anorexia

8. Lower GI abnormalities:(FGALGIAB)

0 - No Diarrhea
1 - Diarrhea Less Than or Equal to 500 mL/day or <280 mL/m²
2 - Diarrhea >500 but Less Than or Equal to 1000 mL/day or 280-555 mL/m²
3 - Diarrhea >1000 but Less Than or Equal to 1500 mL/day or 556-833 mL/m²
4 - Diarrhea >1500 mL/day or >833 mL/m²
*Additional Options Listed Below

9. Liver abnormalities:(FGALVRAB)

0 - Bilirubin <2.0 mg/dL
1 - Bilirubin 2.0-3.0 mg/dL
2 - Bilirubin 3.1-6.0 mg/dL
3 - Bilirubin 6.1-15.0 mg/dL
4 - Bilirubin >15.0 mg/dL

10. Was prophylaxis for GVHD given during this assessment period?(FGPROPI)

1 - Yes
2 - No
3 - Discontinued During This Assessment Period

11. If yes or discontinued during assessment period, specify all immunosuppressants used for GVHD prophylaxis:

a. ATG:(FGPRATG) 1 - Yes 2 - No

b. Bortezomib:(FGPRBORT) 1 - Yes 2 - No

c. Campath:(FGPRCAMP) 1 - Yes 2 - No

d. Cyclophosphamide:(FGPRCYPH) 1 - Yes 2 - No

e. Cyclosporine:(FGPRCYCL) 1 - Yes 2 - No

f. MMF:(FGPRMMF) 1 - Yes 2 - No

- g. Maraviroc:(FGPRMRVR) 1 - Yes 2 - No
- h. Methotrexate:(FGPRMTRX) 1 - Yes 2 - No
- i. Prednisone:(FGPRPRED) 1 - Yes 2 - No
- j. Sirolimus:(FGPRSIR) 1 - Yes 2 - No
- k. Tacrolimus:(FGPTAC) 1 - Yes 2 - No
- l. Other:(FGPROTHR) 1 - Yes 2 - No

Specify other agent used:(FGPROTSP)

12. If GVHD prophylaxis was discontinued during this assessment, record the date:(FGPRDCT) (mm/dd/yyyy)

Chronic GVHD

13. Maximum overall severity of chronic GVHD during this assessment period:(FGSVCGVH)

0 - No Chronic GVHD
1 - Mild
2 - Moderate
3 - Severe

14. Did new clinical signs and/or symptoms of chronic GVHD develop during this assessment period?(FGCGVDVL) 1 - Yes 2 - No

Only initial diagnosis or onset of chronic GVHD should be reported.

15. Date of initial diagnosis/onset of chronic GVHD:(FGCGDGD) (mm/dd/yyyy)

16. Minimum Karnofsky/Lansky Score at time of diagnosis:(FGDGKLN)

01 - 100 (Normal; No Complaints/Fully Active)
02 - 90 (Normal Activity/Minor Restriction in Strenuous Play)
03 - 80 (Normal Activity with Effort/Restricted in Strenuous Play)
04 - 70 (Unable to Carry On Normal Activity/Less Time Spent in Play)
05 - 60 (Requires Occasional Assistance/Minimal Active Play)
*Additional Options Listed Below

17. Minimum platelet count at time of diagnosis:(FGDGPLT) (xxxxxx) /mm³

18. Alkaline phosphatase at time of diagnosis:(FGDGALKP) (xxx) Units/L

19. Weight at time of diagnosis:(FGDGWGT) (xxx.x) kg

20. Total bilirubin at time of diagnosis:(FGDGBILI) (xx.x) mg/dL

21. Did the patient have an erythematous or maculopapular rash at the time of diagnosis?(FGRSDIAG) 1 - Yes 2 - No

22. Was diarrhea, nausea, vomiting or liver function abnormalities present at the time of diagnosis?(FGDRDIAG) 1 - Yes 2 - No

Indicate the maximum severity of involvement for the following organ systems during this assessment period.

Skin/Hair

23. Extent of skin involvement:(FGSKNINV)

0 - No Symptoms
1 - <18% BSA with disease signs but NO sclerotic features
2 - 19-50% BSA OR involvement with superficial sclerotic features not hidebound (able to pinch)
3 - >50% BSA OR deep sclerotic features hidebound OR impaired mobility, ulceration, severe pruritis

If there is skin involvement, indicate the type of rash:

- a. Lichenoid:(FGRSLICH) 1 - Yes 2 - No
- b. Maculopapular:(FGRSMACU) 1 - Yes 2 - No
- c. Sclerodermatous:(FGRSSCLR) 1 - Yes 2 - No
- d. Other:(FGRSOTHR) 1 - Yes 2 - No

Specify other rash:(FGRSOTSP)

Ocular

24. Xerophthalmia:(FGXEROPH)

0 - No Symptoms
1 - Dry Eyes but Not Requiring Therapy
2 - Dryness of Eyes or Inflammation Requiring Therapy

Oral

25. Mucositis/ulcers (functional): (FGMUCOS)

- 0 - No Symptoms
- 1 - Minimal Symptoms, Normal Diet
- 2 - Symptomatic but Can Eat and Swallow Modified Diet
- 3 - Symptomatic and Unable to Adequately Aliment or Hydrate Orally

Pulmonary

26. Bronchiolitis obliterans: (FGBRNCH)

- 1 - Yes, Histologic diagnosis
- 2 - Yes, Clinical diagnosis
- 3 - No
- 4 - Unknown

27. FEV1: (FGFEV1VL)

(xxx) %

Record the lowest value during this assessment period.

28. Date FEV1 obtained: (FGFEV1DT)

(mm/dd/yyyy)

29. FVC: (FGFVCVL)

(xxx) %

Record the value at the time of the lowest FEV1 measurement.

30. DLCO: (FGDLCOVL)

(xxx) %

Record the value at the time of the lowest FEV1 measurement.

Gastrointestinal

31. Esophagus: (FGESOPH)

- 0 - No Symptoms
- 1 - Symptoms, Confirmed with Diagnostic Procedure

32. Nausea and vomiting: (FGNAUSVM)

- 0 - No Protracted Nausea and Vomiting
- 1 - Persistent Nausea, Vomiting or Anorexia

33. Diarrhea: (FGDIARH)

- 0 - None
- 1 - Persisting Less Than 2 Weeks
- 2 - Persisting More Than 2 Weeks

Hepatic

Record the highest value during this assessment period for the following:

	Highest Value	Date Sample Obtained
34. Bilirubin:	(FGBILI) <input type="text"/> (xx.x) mg/dL	(FGBLIDT) <input type="text"/> (mm/dd/yyyy)
35. ALT:	(FGALT) <input type="text"/> (xxxx) Units/L	(FGALTDT) <input type="text"/> (mm/dd/yyyy)
36. AST:	(FGAST) <input type="text"/> (xxxx) Units/L	(FGASTDT) <input type="text"/> (mm/dd/yyyy)
37. Alkaline Phosphatase:	(FGALKPH) <input type="text"/> (xxxx) Units/L	(FGAKPHDT) <input type="text"/> (mm/dd/yyyy)

Genitourinary

38. Non-infective vaginitis: (FGVAGNIT)

- 0 - No Symptoms or Not Applicable
- 1 - Mild, Intervention Not Indicated
- 2 - Moderate, Intervention Indicated
- 3 - Severe, Not Relieved with Treatment; Ulceration

Musculoskeletal

39. Contractures: (FGCONTRC)

- 0 - No Symptoms/Undefined
- 1 - Mild Joint Contractures
- 2 - Moderate Joint Contractures
- 3 - Severe Joint Contractures

40. Myositis: (FGMYOSIT)

1 - Yes 2 - No

Hematologic

41. Eosinophilia: (FGEOSINP) 1 - Yes 2 - No

Other

42. Serositis: (FGSEROS) 1 - Yes 2 - No

43. Fascitis: (FGFASCIT) 1 - Yes 2 - No

44. Was there any other organ involvement? (FGOTORGN) 1 - Yes 2 - No

Specify other organ involvement (FGOTORSP)

Biopsies Performed During this Assessment Period

45. Were any biopsies performed during this assessment period for suspected GVHD? (FGBIOPSY) 1 - Yes 2 - No

If yes, record the type, date, and result of any biopsies performed for suspected GVHD below.

Type of Biopsy:	If Other, Specify:	Date of Biopsy:	Result of Biopsy:
46. (FGBIO1TY) 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	(FGBIO1SP) <input type="text"/>	(FGBIO1DT) <input type="text"/> (mm/d/yyyy)	(FGBIO1RS) 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
47. (FGBIO2TY) 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	(FGBIO2SP) <input type="text"/>	(FGBIO2DT) <input type="text"/> (mm/d/yyyy)	(FGBIO2RS) 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
48. (FGBIO3TY) 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	(FGBIO3SP) <input type="text"/>	(FGBIO3DT) <input type="text"/> (mm/d/yyyy)	(FGBIO3RS) 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
49. (FGBIO4TY) 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	(FGBIO4SP) <input type="text"/>	(FGBIO4DT) <input type="text"/> (mm/d/yyyy)	(FGBIO4RS) 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
50. (FGBIO5TY) 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	(FGBIO5SP) <input type="text"/>	(FGBIO5DT) <input type="text"/> (mm/d/yyyy)	(FGBIO5RS) 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal
51. (FGBIO6TY) 1 - Skin Biopsy 2 - Oral Biopsy 3 - Upper GI Biopsy 4 - Lower GI Biopsy 5 - Liver Biopsy *Additional Options Listed Below	(FGBIO6SP) <input type="text"/>	(FGBIO6DT) <input type="text"/> (mm/d/yyyy)	(FGBIO6RS) 1 - Positive GVHD 2 - Negative GVHD 3 - Equivocal

GVHD Therapy

52. Was a specific therapy used to **treat** chronic GVHD during this assessment period?(FGCHRTRT)

- 1 - Yes, Initiated this Assessment period
- 2 - Yes, Continuing from Previous Assessment Period
- 3 - No

Therapies used for GVHD prophylaxis should not be recorded here. Only report therapies that were initiated during this assessment period. Treatment is defined as increasing the dose of an ongoing agent or addition of a new agent. Adjusting a drug taper does not qualify as treatment.

53. Date chronic GVHD treatment initiated:(FGCTRDT) (mm/dd/yyyy)

If the date is out of range because the therapy was initiated during a previous assessment period, it should be entered on the previous form.

If yes, indicate whether or not the agents listed below were used to **treat** chronic GVHD during this assessment period:

- a. ALS, ALG, ATS, ATG:(FGTHATG) 1 - Yes 2 - No
- b. Azathioprine:(FGTHAZAT) 1 - Yes 2 - No
- c. Cyclosporine:(FGTHCYCL) 1 - Yes 2 - No
- d. Systemic Corticosteroids:(FGTHSYCO) 1 - Yes 2 - No
- e. Topical Corticosteroids:(FGTHTPCO) 1 - Yes 2 - No
- f. Thalidomide:(FGTHTHAL) 1 - Yes 2 - No
- g. Tacrolimus (FK 506, Prograf):(FGHTTAC) 1 - Yes 2 - No
- h. Mycophenolate Mofetil (MMF, Cellcept):(FGTHMMF) 1 - Yes 2 - No
- i. PUVA (Psoralen and UVA):(FGTHPUVA) 1 - Yes 2 - No
- j. ECP (Extra-corporeal Photopheresis):(FGTHECP) 1 - Yes 2 - No
- k. Sirolimus (Rapamycin):(FGTHSIR) 1 - Yes 2 - No
- l. Etrretinate:(FGTHETR) 1 - Yes 2 - No
- m. Lamprene:(FGTHLAMP) 1 - Yes 2 - No
- n. Etanercept:(FGTHETAN) 1 - Yes 2 - No
- o. Zenapax (Daclizumab):(FGTHZENA) 1 - Yes 2 - No
- p. Chloroquine Phosphate:(FGTHCHPH) 1 - Yes 2 - No
- q. In Vivo Anti T-lymphocyte Monoclonal Antibody:
(FGTHMAB)

Specify in vivo anti T-lymphocyte monoclonal antibody used:(FGTHMBSP)

- r. In Vivo Immunotoxin:(FGTHIMM) 1 - Yes 2 - No

Specify in vivo immunotoxin use:(FGTHIMSP)

- s. Other:(FGTHOTHR) 1 - Yes 2 - No

Specify other agent used:(FGTHOTSP)

Comments:(FGVCOMM)

Additional Selection Options for FGV

Lower GI abnormalities:

5 - Severe Abdominal Pain with or without Ileus, or Stool with Frank Blood or Melena

Minimum Karnofsky/Lansky Score at time of diagnosis:

06 - 50 (Requires Considerable Assistance/No Active Play)

07 - 40 (Disabled/Able to Initiate Quiet Activities)

08 - 30 (Severly Disabled/Needs Assistance for Quiet Play)

09 - 20 (Very Sick/Limited to Very Passive Activity)

10 - 10 (Moribund; Completely Disabled)

11 - 0 (Dead)

Biopsy Type 1

6 - Lung Biopsy

7 - Other, Specify