Site Number: __ __ __ __ Screening ID: __ __ __ __ - __ First 3 Letters of First Name: __ __ __

Complete this form for all prescribed changes in coded MMF study medication. With the exception of very short-term changes (less than 1 week), a *separate* form should be completed for all study medication changes, regardless of the reason for the change. Changes can be an alteration of dose and/or the frequency of administration.

A. REPORT INFORMATION

1. Date of report: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

2. Last attended study visit? *(check one)*

☐ 2	Baseline	☐ 6	Week 4	☐ 14	Month 9	☐ 26	Month 21
☐ 3	Week 1	☐ 7	Month 2	☐ 17	Month 12	☐ 29	Month 24
☐ 4	Week 2	☐ 8	Month 3	☐ 20	Month 15		
☐ 5	Week 3	☐ 11	Month 6	☐ 23	Month 18		

B. STUDY MEDICATION CHANGE INFORMATION

1. Date the study medication change became effective: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

Indicate the following information regarding the old and new dosing schedules:

	2. Old Schedule	3. New Schedule
a. Daily dose of MMF/placebo:	__ __ __ __ mg	__ __ __ __ mg
b. Frequency of dosing:	☐ 1 Once a day ☐ 2 Twice daily ☐ 3 Three times per day	☐ 1 Once a day ☐ 2 Twice daily ☐ 3 Three times per day

4. Indicate reason(s) for change in dosing schedule:

a. GI Toxicity *(e.g. diarrhea, nausea, vomiting, gastritis, or anorexia)*?	Y	N	c. Neutropenia?	Y	N
b. Leukopenia?	Y	N	d. Other?	Y	N

IF OTHER,
1. Specify: _____

* If reason for change involved an adverse event complete an Adverse Event Report Form (**MMF07)**

Initials (first, middle, last) of person completing this form: __ __ __ (F M L)

Date form completed: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "" if the desired information is permanently unavailable (i.e. will not be known in any future updates).*