IMACS FORM 01A: CORE PATIENT DATA

To be completed at study entry only

Subject's IMACS number _____

Assessor _____

Date of assessment (mm/dd/yy) _____

Assessment number _____

Type of Study: Therapeutic Trial_____ Natural History Study_____ Other_____

Name of Study:_____

Age at time of Enrollment: ___ Years ____ Months Gender: Male____ Female____
Ethnicity: ___Hispanic or Latino ___ Not Hispanic or Latino ____Unknown/Not reported
Race: Check all that apply:

- ☐ White or Caucasian
- ☐ African-American or Black
- ☐ Asian or Asian American, Pacific Islander
- ☐ Native American or Alaskan Native
- ☐ Other (please specify)_____
- ☐ Unknown/Not reported

Date patient first noticed first myositis symptom (mm/yy): ____/____
Date patient first noticed muscle weakness (mm/yy): ____/____
Date diagnosis made (mm/yy): ____/____
Date of first appropriate treatment for IIM (mm/yy): ____/____

Myositis Criteria: *Criteria for diagnosis of PM/DM*	**Yes**	**No**	**Not Assessed**
Absence of other forms of myopathy, including inclusion body, metabolic, inherited or infectious forms	☐	☐	☐
Symmetric proximal muscle weakness	☐	☐	☐
Rash consisting of heliotrope and/or Gottron's papules/sign	☐	☐	☐
Elevation in serum skeletal muscle enzymes:	☐	☐	☐
Creatine Kinase — *Maximum Value*: ____ *Upper Limit Normal*: ____			
Aldolase — *Maximum Value*: ____ *Upper Limit Normal*: ____			
Lactate dehydrogenase — *Maximum Value*: ____ *Upper Limit Normal*: ____			
Aspartate aminotransferase (AST, SGOT) — *Maximum Value*: ____ *Upper Limit Normal*: ____			
Alanine aminotransferase (ALT, SGPT) — *Maximum Value*: ____ *Upper Limit Normal*: ____			
EMG findings consistent with myositis	☐	☐	☐
Muscle biopsy findings consistent with myositis	☐	☐	☐

IBM Criteria: *Completed only in IBM Patients*	**Yes**	**No**	**Not Assessed**
Characteristic Features – Inclusion Criteria A. Clinical features:			
1. Duration of illness > 6 months	☐	☐	☐
2. Age of onset > 30 years	☐	☐	☐
3. Muscle weakness must affect proximal and distal muscles of arms and legs *and* patient must exhibit at least one of the following features:			
a. Finger flexor weakness	☐	☐	☐
b. Wrist flexor > wrist extensor weakness	☐	☐	☐
c. Quadriceps muscle weakness (= or < grade 4 MRC)	☐	☐	☐
B. Laboratory features:			
1. Serum creatine kinase < 12 times normal	☐	☐	☐
2. Muscle biopsy:			
a. Inflammatory myopathy characterized by mononuclear cell invasion of nonnecrotic muscle fibers	☐	☐	☐
b. Vacuolated muscle fibers	☐	☐	☐
c. Either:			
(i) intracellular amyloid deposits (must use fluorescent method of identification before excluding the presence of amyloid) or	☐	☐	☐
(ii) 15 – 18-nm tubulofilaments by electron microscopy	☐	☐	☐
3. Electromyography must be consistent with features of an inflammatory myopathy (however, long duration potentials are commonly observed and do not exclude diagnosis of sporadic inclusion body myositis	☐	☐	☐

Myositis Clinical and Serologic Group

Myositis Primary Clinical Group:
Select One: ○ Adult OR ○ Juvenile
Select One:
○ Polymyositis
○ Dermatomyositis
○ Inclusion body myositis
○ Other: please clarify_____

Does the patient have Overlap Myositis, defined by myositis plus another defined connective tissue or autoimmune disease? ☐Yes ☐No,
If yes, which other connective tissue or autoimmune diseases?_____

Does the patient have Cancer associated myositis? (i.e., Diagnosed with cancer, excluding focal squamous cell carcinoma of the skin or focal cervical carcinoma or prostate carcinoma in situ) within 2 years of myositis diagnosis)
☐Yes ☐No; If yes, which cancer_____

Severity of Myositis at Onset:
☐ 1 = mild ☐2 = Moderate ☐ 3 = Severe ☐ 4 = Extremely severe

Autoantibodies Tested at Any Time During Illness Course:

Autoantibody	**Result** (Check One)	**Assay Used** (Check all that apply)	**Lab Tested**
ANA Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested Titer: _____	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
Jo-1 Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
SRP Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
Mi-2 Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
P155/140 (TIF1-γ) Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
MJ/NXP-2 Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
MDA-5 Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
HMGCR Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
PL-7 (Alanyl) Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____

Autoantibody	**Result** (Check One)	**Assay Used** (Check all that apply)	**Lab Tested**
PL-12 (Threonyl) Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
U1RNP Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
Ro Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
La Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
Ku Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
PM-Scl Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
Other:_____ Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
Other: _____ Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____
Other: _____ Date Tested:_ _/_ _/_ _ _ _	☐ Negative ☐ Positive ☐ Not Tested	☐ELISA ☐EIA ☐Immunodiffusion ☐Immunoprecipitation ☐Immunofluorescence ☐Immunoprecipitation - Immunoblot ☐Line Blot ☐Multiplex Bead Array Assays ☐Unknown ☐Other, please specify: _____	☐OMRF ☐RDL ☐ARUP ☐Quest ☐Mayo ☐Other, please specify:_____

IMACS FORM 01B: CORE PATIENT DATA

To Be Completed At Each Assessment

Subject's IMACS number _____

Assessor _____

Date of assessment (mm/dd/yy) _____

Assessment number _____

Weight (kg):_____Height (cm):_____

Patient's Other Diagnoses (Top 5) (Co-Morbid Conditions)

1._____
2._____
3. _____
4. _____
5. _____

Apparent Clinical Course (check all that apply):

☐ Monocyclic: full recovery within 2 years without relapse (with or without drug therapy)

☐ Chronic polycyclic: prolonged, relapsing course with one or more relapses occurring between periods of inactive disease

☐ Chronic continuous: persistent disease for longer than 2 years despite drug therapy and which is never inactive

☐ Undefined (illness < 2 years)

☐ Other:_____

ACR Functional Status (1991 revised):

Circle worst grade ever (see definitions below): ☐I ☐II ☐III ☐IV

Circle current grade (see definitions below) ☐I ☐II ☐III ☐IV

I. Completely able to perform usual activities of daily living (self care, vocational and avocational;
II. Able to perform usual self-care and vocational activities, but limited avocational activities;
III. Able to perform usual self-care activities, but limited in vocational and avocational activities;
IV. Limited in ability to perform usual self-care, vocational and avocational activities.

If patient's disease is currently active, specify the duration of active disease for this episode/flare of activity to present time: _____ months

Duration of active disease from diagnosis to present assessment (exclude periods of inactive disease) _____ months

If patient's myositis is currently completely inactive,

A. How many months has the patient's myositis been inactive (based on clinical and laboratory assessment), with or without medication? ____mo.
B. If the patient is not taking medications now, how many months has the patient's myositis been inactive (based on clinical and laboratory assessment) off all medications for myositis (i.e. in remission)? ____ mo.

Signs/Symptoms During Illness Course: Were the following present ever during the illness course?

Sign/Symptom	Ever Present?		
	Present	Absent	Unknown
Pericarditis/myocarditis	☐	☐	☐
Arrhythmia	☐	☐	☐
Interstitial lung disease	☐	☐	☐
Dysphagia	☐	☐	☐
Dysphonia	☐	☐	☐
GI ulceration	☐	☐	☐
Cutaneous ulceration	☐	☐	☐
Erythroderma (extensive areas of confluent erythema, both sun exposed and non-sun exposed skin; can involve entire body)	☐	☐	☐
Calcinosis	☐	☐	☐
Arthritis	☐	☐	☐
Other thought important to prognosis *Specify*:	☐	☐	☐
Other thought important to prognosis *Specify*:	☐	☐	☐
Other thought important to prognosis *Specify*:	☐	☐	☐

Medications	**Never Ever Current Unknown**	***If Current,***	
		Current Dose	***OR*** **Dose per Weight**
Nonsteroidal Anti-Inflammatory Drugs or COX-2 inhibitors- specify:_____	☐ ☐ ☐ ☐	____mg/day	__mg/kg/day
Prednisone, Oral (Prednisolone, Medrol, other corticosteroids)-specify:____	☐ ☐ ☐ ☐	____mg/day	___mg/kg/day
Intravenous methylprednisolone	☐ ☐ ☐ ☐ **Current frequency**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2xMonthly☐ Other, specify:------	___mg/ infusion	___mg/kg/infusion
Topical steroids	☐ ☐ ☐ ☐ **Current frequency of application**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2x Monthly☐ Other, specify:-----	NA	NA
Topical tacrolimus (Protopic) or picrolimus	☐ ☐ ☐ ☐ **Current frequency of application**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2x Monthly☐ Other, specify:------	NA	NA
Disease Modifying Antirheumatic Drugs (DMARDS)			
Methotrexate **Mode of Administration (check all that apply):** Oral☐ Subcutaneous☐ IM☐ IV☐ Unknown☐	☐ ☐ ☐ ☐	____mg/week	___mg/kg/week
Hydroxychloroquine (Plaquenil)	☐ ☐ ☐ ☐	____mg/day	___mg/kg/day
Azathioprine (Imuran)	☐ ☐ ☐ ☐	____mg/day	___mg/kg/day
Cyclosporin A (Sandimmune or Neoral)	☐ ☐ ☐ ☐	____mg/day	___mg/kg/day
Tacrolimus (FK 506)	☐ ☐ ☐ ☐	____mg/day	___mg/kg/day
Leflunomide (ARAVA)	☐ ☐ ☐ ☐	____mg/day	___mg/kg/day
Cyclophosphamide (Cytoxan) IV	☐ ☐ ☐ ☐ **Current frequency of infusion**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2x Monthly☐ Other, specify:--------	____mg/infusion	Dose per BSA: ____mg/m^2/infusion
Cyclophosphamide (Cytoxan) po	☐ ☐ ☐ ☐ **Current frequency of dosage**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2xMonthly☐ Other, specify:------	____mg/dosage	___mg/kg/dosage
Etanercept (Enbrel)	☐ ☐ ☐ ☐	____mg/week	____mg/kg/week
Infliximab (Remicaide)	☐ ☐ ☐ ☐ **Current frequency of infusion**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2xMonthly☐ Other, specify:-------	____mg/infusion	___mg/kg/infusion

Medications	Never Ever Current Unknown	***If Current,*** Current Dose	***OR*** Dose per Weight
Kineret (Anakinra)	☐ ☐ ☐ ☐	___mg/day	___mg/kg/day
Intravenous gammaglobulin (IVIG)	☐ ☐ ☐ ☐ **Current frequency of infusion**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2x Monthly☐ Other, specify: __ **Date last administered:**_ _/_ _/_ _ _ _	___gm/infusion	___gm/kg/infusion
Adalimumab (Humira)	☐ ☐ ☐ ☐ **Current frequency of dosage**: Weekly☐ Every 2 Weeks☐ Every 3 weeks☐	_____mg/dosage	__mg/kg/dosage
Mycophenolate mofetil (MMF)	☐ ☐ ☐ ☐	___mg/day	___mg/kg/day
Rituximab (anti-CD20)	☐ ☐ ☐ ☐ **Current number of infusions at the time of last administration: ____** **Date last administered:**_ _/_ _/_ _ _ _	___mg/infusion	___mg/kg/infusion or ___mg/m^2/infusion
Vitamin D	☐ ☐ ☐ ☐ **Current frequency of dosage**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2x Monthly☐ Other, specify: ___	___IU/dosage	___ IU/kg/dosage
Herbal or Nutritional Supplements: Specify: _____	☐ ☐ ☐ ☐ **Current frequency of dosage**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2x Monthly☐ Other, specify: ___	___mg/dosage	___ mg/kg/dosage
Other drugs or biologic agents: Specify: _____	☐ ☐ ☐ ☐ **Current frequency of dosage**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2x Monthly☐ Other, specify: ___	___mg/dosage	___mg/kg/dosage or __ mg/m^2/dosage
Other drugs or biologic agents: Specify: _____	☐ ☐ ☐ ☐ **Current frequency of dosage**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2x Monthly☐ Other, specify: ___	___mg/dosage	___mg/kg/dosage or __ mg/m^2/dosage
Other drugs or biologic agents: Specify: _____	☐ ☐ ☐ ☐ **Current frequency of dosage**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2x Monthly☐ Other, specify: ___	___mg/dosage	___mg/kg/dosage or __ mg/m^2/dosage
Other treatment: Specify: _____	☐ ☐ ☐ ☐ **Current frequency of dosage**: Daily☐ Weekly☐ Monthly☐ Every Other Day☐ Every 2 Weeks☐ 2x Daily☐ 2x Weekly☐ 2x Monthly☐ Other, specify: ___	___mg/dosage	___mg/kg/dosage or __ mg/m^2/dosage