

INSTRUCTIONS: Please answer all questions at time of initial patient presentation and Kawasaki Disease diagnosis.

Section A: KEY IDENTIFYING INFORMATION

- A1. Study Identification Number _____ - _____ - _____
- A2. Acrostic Identifier _____
- A3. Patient Date of Birth _____ / _____ / _____
M M / D D / Y Y Y Y
- A4. Patient gender MALE.....1 FEMALE.....2
- A5. Name of person completing form _____
PRINT FULL NAME
- A6. Date of screening _____ / _____ / _____
M M / D D / Y Y Y Y

Section B: PATIENT INFORMATION

B1. Patient race

WHITE	1
BLACK OR AFRICAN AMERICAN	2
ASIAN	3
AMERICAN INDIAN OR ALASKAN NATIVE.....	4
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	5
MORE THAN ONE RACE	6
a. Specify _____	
Other	99
b. Specify _____	
Unknown	-8

B2. Is patient of Hispanic or Latino origin? YES..... 1 NO2 UNKNOWN -8

B3. Patient's residential zip/postal code _____
(Leave the last space blank for U.S. residents)

B4. Onset of fever _____ / _____ / _____
M M / D D / Y Y Y Y

Section C: INCLUSION CRITERIA

C1. Fever for at least four days YES..... 1 NO2

PRINCIPAL FEATURES OF KAWASAKI DISEASE	YES	NO
C2. Any extremity changes (Peripheral edema, Peripheral erythema, or Periungual desquamation)	1	2
C3. Rash	1	2
C4. Bilateral, conjunctival injection	1	2
C5. Any oral changes (Injected pharynx or lips, Dry fissured lips, or Strawberry tongue)	1	2
C6. Cervical lymphadenopathy (At least one node ≥ 1.5 cm in diameter)	1	2

CORONARY ARTERY ABNORMALITIES

C7. Echocardiographic evidence of coronary abnormalities

YES 1 NO.....2 (D1) NOT DONE..... 3 (D1)

a. RCA or LAD body surface area-adjusted dimension z-score >2.5

YES 1 NO2

b. Japanese Ministry of Health criteria met, defined as internal lumen diameter of >3 mm in children <5 years old or >4 mm in children 5 years and older

YES 1 NO2

Section D: EXCLUSION CRITERIA

Answer all questions:

	YES	NO
D1. Patient past the 10 th day of illness	1	2
D2. Treatment with gamma globulin prior to enrollment	1	2
D3. Treatment with steroids, other than inhaled forms, within 2 weeks of enrollment	1	2
D4. Believed to have another disease known to mimic Kawasaki disease (e.g., group A Streptococcus or Staph aureus)	1	2
D5. Previous diagnosis of Kawasaki disease	1	2
D6. Suspected infection that would contraindicate steroid use (e.g., Herpes)	1	2
D7. Known hypersensitivity to IVMP or its components	1	2
D8. Other contraindications to steroid therapy	1	2
D9. Unable to take aspirin	1	2

Section E: TRIAL ELIGIBILITY

E1. Patient is eligible for trial based on at least 4 days of fever **AND**:
 (Circle the **first** applicable choice)

AT LEAST 4 of 5 PRINCIPAL FEATURES.....	1
AT LEAST 2 of 5 PRINCIPAL FEATURES AND Z-SCORE >2.5 IN <6 MO. OLD	2
AT LEAST 3 of 5 PRINCIPAL FEATURES AND Z-SCORE >2.5 IN ≥6 MO. OLD	3
AT LEAST 1 of 5 PRINCIPAL FEATURES AND JAPANESE MINISTRY OF HEALTH CRITERIA FOR CORONARY ARTERY ABNORMALITY	4
PATIENT DOES NOT MEET THE ABOVE KAWASAKI DISEASE CRITERIA	5

Patient meets trial eligibility requirements if:

- All answers in Section D are 'NO' and
- Question E1 is NOT equal to 5

E2. Does patient meet all inclusion and no exclusion criteria?

YES 1 NO 2 (END)

Section F: PATIENT CONSENT

F1. Parent/Caregiver signed Informed Consent Form

YES.....1 NO.....2 (F2)

a. Date enrolled/signed consent

$\frac{\quad}{M} \frac{\quad}{M} / \frac{\quad}{D} \frac{\quad}{D} / \frac{\quad}{Y} \frac{\quad}{Y} \frac{\quad}{Y} \frac{\quad}{Y}$ (G1)

F2. Reason for not signing Informed Consent Form: (Circle the **first** applicable choice)

SHORT NOTICE..... 1

a. If short notice, specify reason:

INVESTIGATOR NOT NOTIFIED1

INVESTIGATOR NOT AVAILABLE.....2

FAMILY NOT AVAILABLE3

OTHER REASON FOR SHORT NOTICE...4

a.1. Specify: _____

REFUSAL BY FAMILY..... 2

PEDIATRICIAN/REFERRING PHYSICIAN DID NOT WANT PATIENT IN STUDY..... 3

LANGUAGE BARRIER..... 4

OTHER99

a. Specify other reason _____

STOP—End of form for patients not signing Informed Consent Form
For consenting patients, proceed to next page and complete randomization now

