INSTRUCTIONS: Complete one form for each adverse event.

Section A: KEY IDENTIFYING INFORMATION

A1. Study Identification Number ___ ___ - ___ ___ ___ ___ ___ - ___

A2. Acrostic Identifier ___ ___ ___ ___ ___ ___

A3. Date of adverse event ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

A4. Time event started/was diagnosed ___ ___ : ___ ___
a. AM....................... 1 PM .... 2 24-Hour.................. 3

A5. Date of form completion ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

A6. Name of person completing form ______________________________
PRINT FULL NAME

Section B: ADVERSE EVENT ASSESSMENT

B1. Adverse event occurrence INPATIENT............. 1 **(B2)** OUTPATIENT 2

a. Was patient hospitalized for this event?
YES .... 1 NO........................ 2
Complete Hospital Readmission Form K012

B2. Type of adverse event

		YES	NO
a.	Kawasaki Disease-related	1	2
b.	Other cardiac-related	1	2
c.	Infection	1	2
d.	Allergic reaction	1	2
e.	Other	1	2

B3. Describe event ______________________________
____
____

B4. Event code **(See Code List E)** ___ - ___ ___ ___ ___

a. Specify ______________________________

B5. Was this event related to IVMP/Placebo?
NOT RELATED.....1 POSSIBLY RELATED ....2 PROBABLY RELATED 3

B6. Was this event related to IVIG?

NOT RELATED.....1 POSSIBLY RELATED........2 PROBABLY RELATED....3

B7. Was this event related to a study procedure?

NOT RELATED.....1 **(B8)** POSSIBLY RELATED........2 PROBABLY RELATED...3

a. Specify procedure ______________________________

B8. Was event resolved YES ....1 NO .... 2 **(B9)**

a. Date event resolved ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

B9. Seriousness of event

NOT SERIOUS.. 1
MODERATELY SERIOUS 2
SERIOUS 3
DEATH 4

Section C: ABNORMAL LABORATORY FINDINGS

C1. Any abnormal laboratory findings related to event?

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

a. Specify ______________________________

Section D: TREATMENT

D1. Number of medications for treatment of adverse event **(See Code List D)** ___ ___

	Medication Code	Medication Name Worksheet
a.	___ ___ . ___ ___	
b.	___ ___ . ___ ___	
c.	___ ___ . ___ ___	
d.	___ ___ . ___ ___	
e.	___ ___ . ___ ___	
f.	___ ___ . ___ ___	

D2. Patient received supplemental oxygen for event YES ....1 NO 2

FAX COMPLETED FORM WITHIN 24 HOURS OF EVENT TO:
ATTN: PHN DATA MANAGER
FAX NUMBER: 617 - 923 - 4176