Section A: KEY IDENTIFYING INFORMATION

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

A2. Acrostic Identifier ___ ___ ___ ___ ___

A3. Date of initial treatment ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

A4. Name of person completing form _____
PRINT FULL NAME

Section B: STUDY DRUG/PLACEBO DATA

B1. Date study drug/placebo **started** ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

B2. Time study drug/placebo **started** ___ ___ : ___ ___

a. AM ..... 1 PM 2 24-HOUR 3

B3. Volume study drug/placebo (from syringe) ___ ___ ___ . ___ mL

B4. Initial volume **modified** YES ..... 1 NO ..... 2 **(B5)**

a. Modified volume ___ ___ ___ ___ mL

B5. Therapy **interrupted** YES ..... 1 NO ..... 2 **(B6)**

Reason for interruption (Answer ALL questions a-d)

a. Stopped by physician YES ..... 1 NO 2

b. Reaction to study drug/placebo YES ..... 1 NO 2
If 'YES', complete Adverse Event Form K010

c. Dislodged IV YES ..... 1 NO 2

d. Other YES ..... 1 NO ..... 2 **(B6)**

d.1. Specify: _____

B6. Was therapy **completed** YES ..... 1 NO ..... 2 **(C1)**

a. Date study drug/placebo completed ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

b. Time study drug/placebo completed ___ ___ : ___ ___

b.1. AM ..... 1 PM 2 24-HOUR 3

Section C: IVIG PRE-TREATMENT DATA

C1. Pre-medication with Benadryl® (diphenhydramine HCl)
YES..... 1 NO ..... 2 **(D1)** UNKNOWN .....-8 **(D1)**

C2. Date Benadryl® given ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

C3. Time Benadryl® given ___ ___ : ___ ___

a. AM .....1 PM 2 24-HOUR 3

C4. Route IV .....1 ORAL……2

C5. Dose (1 mg/kg) ___ ___ mg

Section D: IVIG DATA

D1. Date IVIG **started** ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

D2. Time IVIG **started** ___ ___ : ___ ___

a. AM .....1 PM 2 24-HOUR 3

D3. Dose (2 g/kg) ___ ___ ___ g

D4. IVIG brand

GAMMA IV (ARMOUR) 1
GAMMAGUARD S/D (BAXTER) 2
GAMMAGUARD (BAXTER/HYLAND).....3
GAMMIMUNE (MILES/CUTTER) 4
IVEEGAM-EN (BAXTER/HYLAND).....5
PANGLOBULIN (RED CROSS) 6
POLYGAM (RED CROSS).....7
VENOGLOBULIN S (ALPHA).....8
OTHER 99

a. Specify: _____

UNKNOWN.....-8

D5. Initial dose **modified** YES.....1 NO ..... 2 **(D6)**

a. Modified dose ___ ___ ___ g

D6. IVIG therapy **interrupted** YES.....1 NO .....2 **(D7)**

Reason for interruption (Answer ALL questions a-d)

a. Stopped by physician YES.....1 NO 2

b. Reaction to IVIG YES.....1 NO 2
If 'YES', complete Adverse Event Form K010

c. Dislodged IV YES.....1 NO 2

d. Other YES.....1 NO .....2 **(D7)**

d.1. Specify: _____

D7. Was IVIG therapy **completed** YES.....1 NO .....2 **(END)**

a. Date IVIG completed ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

b. Time IVIG completed ___ ___ : ___ ___

b.1. AM ..... 1 PM 2 24-HOUR 3