Protocol ID: P007
Study Name: PRIME
Site: _____

Study Subject ID:_____
Interviewer Name:_____

	Enrollment/Baseline	Day 3-5	Day 14	Day 30	Day 60	Day 90	Day 180	Day 270	Day 360	Transplant	AE/Med/Deviation Logs	SAE	Final Status
PRIME_000_PROBE Link - 2.0	X												
PRIME_001_Eligibility - 1.0	X												
PRIME_015_Exemption Request - 1.0	X												
PRIME_005_Diet - 1.0		X	X	X	X	X	X	X	X	X			
PRIME_007_PhysicalExam - 2.0		X	X	X	X	X	X	X	X	X			
PRIME_008_Laboratory Results - 4.0		X	X	X	X	X	X	X	X	X			
PRIME_009_IV Access Log - 3.0		X		X	X								
PRIME_011_IVIG Infusion - 2.0		X		X	X								
PRIME_050_Research Lab-Blood - 3.0		X			X	X	X		X				
PRIME_050_Research Lab-Blood - 2.0										X			
PRIME_051_Research Lab-Plasma - 3.0		X			X	X	X		X				
PRIME_051_Research Lab-Plasma - 2.0										X			
PRIME_025_Transplant - 2.0										X			
PRIME_013_Concomitant Medications - 6.0											X		
PRIME_020_Adverses Event Log - 3											X		
PRIME_040_Protocol Deviation Log - 3											X		
PRIME_045_SAE-Serious Adverse Event - 6.0												X	
PRIME_035_Final Status - 1.0													X

Enrollment/Baseline:

PRIME_000_PROBE Link - 2.0
PRIME_001_Eligibility - 1.0
PRIME_015_Exemption Request - 1.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Study Name: PRIME
Site: _____
Event Name: Enrollment/Baseline
Event Date: _____

Interviewer Name:_____

PRIME_000_PROBE Link - 2.0

Section Title: PROBE Link

Upload Source Documents

A1. PROBE subject ID *

A2. Date of Birth * *DD-MMM-YYYY*

A3. Date of HPE * *DD-MMM-YYYY*

A4. Date PRIME consent signed * *DD-MMM-YYYY*

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Enrollment/Baseline
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_001_Eligibility - 1.0

Section Title: Inclusion Criteria

Subject is Eligible for PRIME if the following Inclusion Criteria are met.

A1. < 120 days old
* ○ Yes ○ No ○ Unknown

A2. Enrolled in PROBE
* ○ Yes ○ No ○ Unknown

A3. HPE for BA within the previous 3 days
* ○ Yes ○ No ○ Unknown

A4. Subject's gestational age greater than or equal to 36 weeks at enrollment?
* ○ Yes ○ No ○ Unknown

A5. Subject's weight greater than or equal to 2000g at enrollment?
* ○ Yes ○ No ○ Unknown

A6. Informed consent obtained within 3 days following HPE
* ○ Yes ○ No ○ Unknown

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Enrollment/Baseline
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Exclusion Criteria

Subject is Eligible for PRIME if none of the following Exclusion Criteria apply.

B1. Laparoscopic HPE or "Gallbladder Kasai" (cholecysto-portostomy) surgery was performed
* ○ Yes ○ No ○ Unknown

B2. Biliary Atresia Splenic Malformation Syndrome (presence of asplenia, polysplenia or double spleen)
* ○ Yes ○ No ○ Unknown

B3. History of a Hypercoagulable Disorder
* ○ Yes ○ No ○ Unknown

B4. Renal Disease (defined as serum creatinine > 1.0 mg/dl) prior to enrollment, or presence of complex renal anomalies found on imaging
* ○ Yes ○ No ○ Unknown

B5. Evidence of congestive heart failure or fluid overload
* ○ Yes ○ No ○ Unknown

B6. Presence of significant systemic hypertension for age (defined as persistent systolic blood pressure ≥112 mmHg measured on at least 3 occasions following HPE)
* ○ Yes ○ No ○ Unknown

B7. Infants whose mother is known to have Human Immunodeficiency Virus infection
* ○ Yes ○ No ○ Unknown

B8. Infants whose mother is known to be serum HBsAg or Hepatitis C virus antibody positive
* ○ Yes ○ No ○ Unknown

B9. Previous treatment with intravenous immunoglobulin therapy
* ○ Yes ○ No ○ Unknown

B10. Previous treatment with corticosteroid therapy for post-operative treatment of BA
* ○ Yes ○ No ○ Unknown

B11. Previous treatment with any other investigational agent
* ○ Yes ○ No ○ Unknown

B12. History of allergic reaction to any human blood product infusion
* ○ Yes ○ No ○ Unknown

B13. Infants with other severe concurrent illnesses (such as neurological, cardiovascular, pulmonary, metabolic, endocrine, and renal disorders) that would interfere with the conduct and results of the study
* ○ Yes ○ No ○ Unknown

B14. Any other clinical condition that is a contraindication to the use of IVIG
* ○ Yes ○ No ○ Unknown

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Enrollment/Baseline
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Status

C1. Subject Eligibility Status
*

- ○ Eligible
- ○ Eligible by exemption
- ○ Not eligible

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Enrollment/Baseline
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_015_Exemption Request - 1.0

Section Title: Exemption Request
Subtitle: **Complete A1, A2 and A3 of this form to request an eligibility exemption.** **When form is saved, an email will be sent to exemption committee.** **When approval/denial is granted, the DCC will complete items A4 and A5 and an email will be sent to the PI and Coordinator**
Instructions: **Select the Inclusion/Exclusion criteria below that is not met for Eligibility**

A1. Inclusion

- ○ Subject is < 120 days old
- ○ Subject must be enrolled in PROBE
- ○ Had HPE for BA within the previous 72 hrs
- ○ Was > 36 weeks post conception (gestational age)
- ○ Weighed > 2000g
- ○ Written informed consent obtained within 3 days of HPE

A2. Exclusion

- ○ Laparoscopic HPE or gall bladder Kasai (cholecysto-portostomy) surgery was performed
- ○ Biliary atresia splenic malformation syndrome (presence of asplenia- polysplenia or double spleen) detected
- ○ History of a hypercoagulable disorder reported
- ○ Renal Disease (defined as serum creatinine > 1.0 mg/dl) prior to enrollment or presence of complex renal anomalies found on imaging
- ○ Evidence of congestive heart failure or fluid overload
- ○ Presence of significant systemic hypertension for age (defined as persistent systolic blood pressure ≥112 mmHg measured on at least 3 occasions following HPE)
- ○ Mother known to have human immunodeficiency virus infection
- ○ Mother is known to be serum HBsAg or hepatitis C virus antibody positive
- ○ Previously treated with intravenous immunoglobulin therapy
- ○ Previously treated with corticosteroid therapy for BA post-HPE
- ○ Previously treated with any other investigational agent
- ○ History of allergic reaction to any human blood product infusion reported
- ○ Presence of other severe concurrent illnesses (such as neurological-cardiovascular-pulmonary-metabolic-endocrine and renal disorders) that would interfere with the conduct and results of the study
- ○ Presence of any other clinical condition that is a contraindication to the use of IVIG

A3. Reason for Request

A4. Exemption Granted

- ○ Yes
- ○ No

A4a. If No, Reason:

A5. Date of Decision

Day 3-5:

PRIME_005_Diet - 1.0
PRIME_007_PhysicalExam - 2.0
PRIME_008_Laboratory Results - 4.0
PRIME_009_IV Access Log - 3.0
PRIME_011_IVIG Infusion - 2.0
PRIME_050_Research Lab-Blood - 3.0
PRIME_051_Research Lab-Plasma - 3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Study Subject ID:_____
Interviewer Name:_____

Site: _____
Event Name: Day 3-5
Event Date: _____

PRIME_005_Diet - 1.0

Section Title: Diet

A1. What type of diet is the child on? (check all that apply)

- ☐ Human Milk
- ☐ Cow's Milk Based Formula
- ☐ Soy Formula
- ☐ Specialized Formula
- ☐ Parental Nutrition
- ☐ Solid Food
- ☐ Not Specified

A1a. Type of Human Milk

- ☐ Breast Milk
- ☐ Banked Human Milk
- ☐ Not Specified

A1b. Type of Cow's Milk

- ☐ Standard Infant Formula
- ☐ Follow-On Formula
- ☐ Not Specified

A1c. Type of Soy Milk

- ☐ Prosobee
- ☐ Isomil
- ☐ Other Soy Formula — Other Soy, Specify Type
- ☐ Not Specified

A1d. Type of Specialized Milk

- ☐ Alimentum
- ☐ Pregistimil
- ☐ Neocate
- ☐ Low Lactose
- ☐ Nutramigen
- ☐ Other Specialized Formula — Other Specialized, Specify Type
- ☐ Not Specified

A1e. Type of Parental Nutrition

- ☐ Total
- ☐ Partial
- ☐ Not Specified

A2. How is the child fed? (check all that apply)

Indicate Feeding Method

- ☐ Oral
- ☐ Nasogastric
- ☐ Nasoenteric
- ☐ Gastrostomy
- ☐ Gastrojejunostomy
- ☐ Lejunostomy
- ☐ Intravenous
- ☐ Not Specified

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_007_PhysicalExam - 2.0

Section Title: Athropometrics

Upload source documents

A1. Height/Length
(cm) ☐ Not Done

A2. Weight
(kg) ☐ Not Done

A3. Head Circumference
(cm) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Vital Signs

B1. Systolic BP

(mmHg) ☐ Not Done

B2. Diastolic BP

(mmHg) ☐ Not Done

B3. Heart Rate

(beats per min) ☐ Not Done

B4. Respiratory Rate

(breaths per min) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Physical Exam

Skin Exam

C1. Rash *
- ○ Present
- ○ Absent
- ○ Not Done

C1a. If present indicate type
- ☐ Eczema
- ☐ Viral Exanthems
- ☐ Acute Allergic (hives; erythema multiforme)
- ☐ Diaper Rash (candida)
- ☐ Other

If Other Rash, Specify:

C2. Urticaria *
- ○ Present
- ○ Absent
- ○ Not Done

C3. Jaundice *
- ○ Present
- ○ Absent
- ○ Not Done

C3a. If present, indicate location
- ☐ Skin
- ☐ Sclera

C4. Liver Exam *
- ○ Performed
- ○ Not Performed

C4a. Liver Location
- ○ Left Side
- ○ Midline
- ○ Right Side
- ○ Not Palpable
- ○ Not Done

C4b. Liver Span (cm at mid-clavicular line) ND or NP
- ○ Not Done
- ○ Not Palpable

C4c. Liver Edge (cm below costal margin) ND or NP
- ○ Not Done
- ○ Not Palpable

C4d. Liver Edge (cm below xiphoid) ND or NP
- ○ Not Done
- ○ Not Palpable

C4e. Liver Texture
- ○ Soft
- ○ Firm
- ○ Hard
- ○ Nodular and Hard
- ○ Not Palpable

C5. Spleen Exam *
- ○ Performed
- ○ Not Performed

○ Not Palpable

C5a. Spleen Location

○ Left Side
○ Midline
○ Right Side

C5b. Spleen Size (cm below the left (right) costal margin) ☐ Not Done

C6. Ascites
*

○ Present
○ Absent
○ Not Done

C7. Extremities: Peripheral Edema
*

○ Present
○ Absent
○ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_008_Laboratory Results - 4.0

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

Upload Source document file

A1. Total Bilirubin	(mg/dl)	Date	☐ Not Done
A2. Indirect Bilirubin	(mg/dl)	Date	☐ Not Done
A3. Direct Bilirubin	(mg/dl)	Date	☐ Not Done
A4. Unconjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A5. Conjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A6. AST	(U/L)	Date	☐ Not Done
A7. ALT	(U/L)	Date	☐ Not Done
A8. Alkaline Phosphatase	(U/L)	Date	☐ Not Done
A9. GGTP	(U/L)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Coagulation Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

B1. Prothrombin Time (Sec) Date ☐ Not Done

B2. INR Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Basic Metabolic Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

C1. Sodium (Na)	(mmol/l)	Date	☐ Not Done
C2. Potassium (K)	(mmol/l)	Date	☐ Not Done
C3. Chloride (CI)	(mmol/l)	Date	☐ Not Done
C4. Bicarbonate ($CO_{(2)}$)	(mmol/l)	Date	☐ Not Done
C5. Creatinine	(mg/dl)	Date	☐ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: CBC with Differential

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

D1. Hemoglobin (Hgb)	(g/dl) Date		☐ Not Done
D2. Hematocrit (Hct)	(%) Date		☐ Not Done
D3. RBC	(10^3 / mm^3) Date		☐ Not Done
D4. WBC	(10^3 / mm^3) Date		☐ Not Done
D4a. Neutrophils	(%)	☐ Not Done	
D4b. Bands	(%)	☐ Not Done	
D4c. Lymphocytes	(%)	☐ Not Done	
D4d. Monocytes	(%)	☐ Not Done	
D4e. Eosinophils	(%)	☐ Not Done	
D5. Platelets	(10^3 / mm^3) Date		☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Serum IgG

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

E1. Serum Total lgG (mg/dl) Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

A10. Albumin	(g/dL)	Date	☐ Not Done
A11. Total Protein	(g/dL)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_009_IV Access Log - 3.0

Section Title: Venous Access

Instructions: Complete the information requested for each IV access that was used during this infusion.

- If a line was already in place, select pre-existing.
- If IV access was lost during the infusion and was restarted, click ADD to complete the information on the reinserted line.

Select the one best response for each column below:

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A1. Was an IV Line attempted, inserted, or used for the IVIG infusion at this visit?
*
○ Yes ○ No - End of Form

Which Attempt	Venous Access Type	# of Attempts to Insert IV	Successfully Inserted?	If unsuccessful, why?	If "Other Reason" was selected, Specify below	Location of IV line	Date Attempted/Inserted	Time Inserted	Date Removed	Time Removed	IV Line NOT removed
○ Pre-existing ○ New insertion ○ 1st reinsertion ○ 2nd reinsertion ○ 3rd reinsertion	○ Peripheral intravenous ○ PICC line ○ Central intravenous	○ Pre-existing ○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ >5 ○ UNK	○ Yes ○ No	○ Parents objected ○ # of attempts exceeds hospital policy ○ Infant distressed ○ Unable to access vein ○ Reason unknown ○ Other reason		○ Rt Arm ○ Lft Arm ○ Rt Hand ○ Lft Hand ○ Rt Leg ○ Lft Leg ○ Rt Foot ○ Lft Foot ○ Rt side of Neck ○ Lft side of Neck ○ Torso ○ Scalp ○ Other					☐ Not Removed

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_011_IVIG Infusion - 2.0

Section Title: IVIG Infusion Monitoring

Upload source documents

A1. Was dose administered? *
- ○ Yes
- ○ No

A1a. If No, reason
- ☐ Adverse event
- ☐ Previous dose discontinued
- ☐ IV access lost
- ☐ Caretaker request
- ☐ Other

Other specify

A2. Date dose started | Time dose started | *24 hour clock 0000 format*

A3. Date dose completed or stopped | Time completed or stopped | *24 hour clock 0000 format*

A4. Amount of IVIG in dose (1 gm/kg body weight) gm

A5. Volume of infusion preparation mL

A6. Volume actually infused mL

A7. Was full dose administered?
- ○ Yes
- ○ No

A7a. If No, reason
- ☐ Adverse event
- ☐ IV access lost
- ☐ Caretaker request
- ☐ Other

Other specify

A8. Were there any infusion related adverse events?
- ○ Yes
- ○ No

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_050_Research Lab-Blood - 3.0

Section Title: Research Labs-Whole Blood

A1. Was Whole Blood collected at this visit
* ○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4. Barcode from Whole Blood

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 3-5
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_051_Research Lab-Plasma - 3.0

Section Title: Plasma Specimens

Whole blood is collected, spun down and the plasma is aliquoted. The aliquots are to be frozen and batch shipped at a later date.
A1. Was Blood collected for plasma at this visit?
*

○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4a. Barcode of Aliquot #1

A4b. Barcode of Aliquot #2

A4c. Barcode of Aliquot #3

A4d. Barcode of Aliquot #4

A4e. Barcode of Aliquot #5

A4f. Barcode of Aliquot #6

Day 14:

PRIME_005_Diet - 1.0
PRIME_007_PhysicalExam - 2.0
PRIME_008_Laboratory Results - 4.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 14
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_005_Diet - 1.0

Section Title: Diet

A1. What type of diet is the child on? (check all that apply)

- ☐ Human Milk
- ☐ Cow's Milk Based Formula
- ☐ Soy Formula
- ☐ Specialized Formula
- ☐ Parental Nutrition
- ☐ Solid Food
- ☐ Not Specified

A1a. Type of Human Milk

- ☐ Breast Milk
- ☐ Banked Human Milk
- ☐ Not Specified

A1b. Type of Cow's Milk

- ☐ Standard Infant Formula
- ☐ Follow-On Formula
- ☐ Not Specified

A1c. Type of Soy Milk

- ☐ Prosobee
- ☐ Isomil
- ☐ Other Soy Formula — Other Soy, Specify Type
- ☐ Not Specified

A1d. Type of Specialized Milk

- ☐ Alimentum
- ☐ Pregistimil
- ☐ Neocate
- ☐ Low Lactose
- ☐ Nutramigen
- ☐ Other Specialized Formula — Other Specialized, Specify Type
- ☐ Not Specified

A1e. Type of Parental Nutrition

- ☐ Total
- ☐ Partial
- ☐ Not Specified

A2. How is the child fed? (check all that apply)

Indicate Feeding Method

- ☐ Oral
- ☐ Nasogastric
- ☐ Nasoenteric
- ☐ Gastrostomy
- ☐ Gastrojejunostomy
- ☐ Lejunostomy
- ☐ Intravenous
- ☐ Not Specified

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 14
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_007_PhysicalExam - 2.0

Section Title: Athropometrics

Upload source documents

A1. Height/Length
(cm) ☐ Not Done

A2. Weight
(kg) ☐ Not Done

A3. Head Circumference
(cm) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 14
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Vital Signs

B1. Systolic BP

(mmHg) ☐ Not Done

B2. Diastolic BP

(mmHg) ☐ Not Done

B3. Heart Rate

(beats per min) ☐ Not Done

B4. Respiratory Rate

(breaths per min) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 14
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Physical Exam

Skin Exam

C1. Rash *
- ○ Present
- ○ Absent
- ○ Not Done

C1a. If present indicate type
- ☐ Eczema
- ☐ Viral Exanthems
- ☐ Acute Allergic (hives; erythema multiforme)
- ☐ Diaper Rash (candida)
- ☐ Other

If Other Rash, Specify:

C2. Urticaria *
- ○ Present
- ○ Absent
- ○ Not Done

C3. Jaundice *
- ○ Present
- ○ Absent
- ○ Not Done

C3a. If present, indicate location
- ☐ Skin
- ☐ Sclera

C4. Liver Exam *
- ○ Performed
- ○ Not Performed

C4a. Liver Location
- ○ Left Side
- ○ Midline
- ○ Right Side
- ○ Not Palpable
- ○ Not Done

C4b. Liver Span (cm at mid-clavicular line) ND or NP
- ○ Not Done
- ○ Not Palpable

C4c. Liver Edge (cm below costal margin) ND or NP
- ○ Not Done
- ○ Not Palpable

C4d. Liver Edge (cm below xiphoid) ND or NP
- ○ Not Done
- ○ Not Palpable

C4e. Liver Texture
- ○ Soft
- ○ Firm
- ○ Hard
- ○ Nodular and Hard
- ○ Not Palpable

C5. Spleen Exam *
- ○ Performed
- ○ Not Performed

○ Not Palpable

C5a. Spleen Location

○ Left Side
○ Midline
○ Right Side

C5b. Spleen Size (cm below the left (right) costal margin) ☐ Not Done

C6. Ascites
*

○ Present
○ Absent
○ Not Done

C7. Extremities: Peripheral Edema
*

○ Present
○ Absent
○ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 14
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_008_Laboratory Results - 4.0

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

Upload Source document file

A1. Total Bilirubin	(mg/dl)	Date	☐ Not Done
A2. Indirect Bilirubin	(mg/dl)	Date	☐ Not Done
A3. Direct Bilirubin	(mg/dl)	Date	☐ Not Done
A4. Unconjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A5. Conjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A6. AST	(U/L)	Date	☐ Not Done
A7. ALT	(U/L)	Date	☐ Not Done
A8. Alkaline Phosphatase	(U/L)	Date	☐ Not Done
A9. GGTP	(U/L)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 14
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Coagulation Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

B1. Prothrombin Time (Sec) Date ☐ Not Done

B2. INR Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 14
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Basic Metabolic Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

C1. Sodium (Na)	(mmol/l)	Date	☐ Not Done
C2. Potassium (K)	(mmol/l)	Date	☐ Not Done
C3. Chloride (CI)	(mmol/l)	Date	☐ Not Done
C4. Bicarbonate ($CO_{(2)}$)	(mmol/l)	Date	☐ Not Done
C5. Creatinine	(mg/dl)	Date	☐ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 14
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: CBC with Differential

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

D1. Hemoglobin (Hgb)	(g/dl) Date		☐ Not Done
D2. Hematocrit (Hct)	(%) Date		☐ Not Done
D3. RBC	(10^3 / mm^3) Date		☐ Not Done
D4. WBC	(10^3 / mm^3) Date		☐ Not Done
D4a. Neutrophils	(%)	☐ Not Done	
D4b. Bands	(%)	☐ Not Done	
D4c. Lymphocytes	(%)	☐ Not Done	
D4d. Monocytes	(%)	☐ Not Done	
D4e. Eosinophils	(%)	☐ Not Done	
D5. Platelets	(10^3 / mm^3) Date		☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 14
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Serum IgG

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

E1. Serum Total lgG (mg/dl) Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 14
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Hepatic Function Panel
Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

A10. Albumin	(g/dL)	Date	☐ Not Done
A11. Total Protein	(g/dL)	Date	☐ Not Done

Day 30:

PRIME_005_Diet - 1.0
PRIME_007_PhysicalExam - 2.0
PRIME_008_Laboratory Results - 4.0
PRIME_009_IV Access Log - 3.0
PRIME_011_IVIG Infusion - 2.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_005_Diet - 1.0

Section Title: Diet

A1. What type of diet is the child on? (check all that apply)

- ☐ Human Milk
- ☐ Cow's Milk Based Formula
- ☐ Soy Formula
- ☐ Specialized Formula
- ☐ Parental Nutrition
- ☐ Solid Food
- ☐ Not Specified

A1a. Type of Human Milk

- ☐ Breast Milk
- ☐ Banked Human Milk
- ☐ Not Specified

A1b. Type of Cow's Milk

- ☐ Standard Infant Formula
- ☐ Follow-On Formula
- ☐ Not Specified

A1c. Type of Soy Milk

- ☐ Prosobee
- ☐ Isomil
- ☐ Other Soy Formula — Other Soy, Specify Type
- ☐ Not Specified

A1d. Type of Specialized Milk

- ☐ Alimentum
- ☐ Pregistimil
- ☐ Neocate
- ☐ Low Lactose
- ☐ Nutramigen
- ☐ Other Specialized Formula — Other Specialized, Specify Type
- ☐ Not Specified

A1e. Type of Parental Nutrition

- ☐ Total
- ☐ Partial
- ☐ Not Specified

A2. How is the child fed? (check all that apply)

Indicate Feeding Method

- ☐ Oral
- ☐ Nasogastric
- ☐ Nasoenteric
- ☐ Gastrostomy
- ☐ Gastrojejunostomy
- ☐ Lejunostomy
- ☐ Intravenous
- ☐ Not Specified

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_007_PhysicalExam - 2.0

Section Title: Athropometrics

Upload source documents

A1. Height/Length
(cm) ☐ Not Done

A2. Weight
(kg) ☐ Not Done

A3. Head Circumference
(cm) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Vital Signs

B1. Systolic BP

(mmHg) ☐ Not Done

B2. Diastolic BP

(mmHg) ☐ Not Done

B3. Heart Rate

(beats per min) ☐ Not Done

B4. Respiratory Rate

(breaths per min) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Physical Exam

Skin Exam

C1. Rash *
- ○ Present
- ○ Absent
- ○ Not Done

C1a. If present indicate type
- ☐ Eczema
- ☐ Viral Exanthems
- ☐ Acute Allergic (hives; erythema multiforme)
- ☐ Diaper Rash (candida)
- ☐ Other

If Other Rash, Specify:

C2. Urticaria *
- ○ Present
- ○ Absent
- ○ Not Done

C3. Jaundice *
- ○ Present
- ○ Absent
- ○ Not Done

C3a. If present, indicate location
- ☐ Skin
- ☐ Sclera

C4. Liver Exam *
- ○ Performed
- ○ Not Performed

C4a. Liver Location
- ○ Left Side
- ○ Midline
- ○ Right Side
- ○ Not Palpable
- ○ Not Done

C4b. Liver Span (cm at mid-clavicular line) ND or NP
- ○ Not Done
- ○ Not Palpable

C4c. Liver Edge (cm below costal margin) ND or NP
- ○ Not Done
- ○ Not Palpable

C4d. Liver Edge (cm below xiphoid) ND or NP
- ○ Not Done
- ○ Not Palpable

C4e. Liver Texture
- ○ Soft
- ○ Firm
- ○ Hard
- ○ Nodular and Hard
- ○ Not Palpable

C5. Spleen Exam *
- ○ Performed
- ○ Not Performed

○ Not Palpable

C5a. Spleen Location

○ Left Side
○ Midline
○ Right Side

C5b. Spleen Size (cm below the left (right) costal margin) ☐ Not Done

C6. Ascites
*

○ Present
○ Absent
○ Not Done

C7. Extremities: Peripheral Edema
*

○ Present
○ Absent
○ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_008_Laboratory Results - 4.0

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

Upload Source document file

A1. Total Bilirubin	(mg/dl)	Date	☐ Not Done
A2. Indirect Bilirubin	(mg/dl)	Date	☐ Not Done
A3. Direct Bilirubin	(mg/dl)	Date	☐ Not Done
A4. Unconjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A5. Conjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A6. AST	(U/L)	Date	☐ Not Done
A7. ALT	(U/L)	Date	☐ Not Done
A8. Alkaline Phosphatase	(U/L)	Date	☐ Not Done
A9. GGTP	(U/L)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Coagulation Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

B1. Prothrombin Time (Sec) Date ☐ Not Done

B2. INR Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Basic Metabolic Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

C1. Sodium (Na)	(mmol/l)	Date	☐ Not Done
C2. Potassium (K)	(mmol/l)	Date	☐ Not Done
C3. Chloride (CI)	(mmol/l)	Date	☐ Not Done
C4. Bicarbonate ($CO_{(2)}$)	(mmol/l)	Date	☐ Not Done
C5. Creatinine	(mg/dl)	Date	☐ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: CBC with Differential

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

D1. Hemoglobin (Hgb)	(g/dl) Date		☐ Not Done
D2. Hematocrit (Hct)	(%) Date		☐ Not Done
D3. RBC	(10^3 / mm^3) Date		☐ Not Done
D4. WBC	(10^3 / mm^3) Date		☐ Not Done
D4a. Neutrophils	(%)	☐ Not Done	
D4b. Bands	(%)	☐ Not Done	
D4c. Lymphocytes	(%)	☐ Not Done	
D4d. Monocytes	(%)	☐ Not Done	
D4e. Eosinophils	(%)	☐ Not Done	
D5. Platelets	(10^3 / mm^3) Date		☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Serum IgG

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

E1. Serum Total lgG (mg/dl) Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

A10. Albumin	(g/dL)	Date	☐ Not Done
A11. Total Protein	(g/dL)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_009_IV Access Log - 3.0

Section Title: Venous Access

Instructions: Complete the information requested for each IV access that was used during this infusion.

- If a line was already in place, select pre-existing.
- If IV access was lost during the infusion and was restarted, click ADD to complete the information on the reinserted line.

Select the one best response for each column below:

Upload Source document file

A1. Was an IV Line attempted, inserted, or used for the IVIG infusion at this visit?
*
○ Yes ○ No - End of Form

Which Attempt	Venous Access Type	# of Attempts to Insert IV	Successfully Inserted?	If unsuccessful, why?	If "Other Reason" was selected, Specify below	Location of IV line	Date Attempted/Inserted	Time Inserted	Date Removed	Time Removed	IV Line NOT removed
○ Pre-existing ○ New insertion ○ 1st reinsertion ○ 2nd reinsertion ○ 3rd reinsertion	○ Peripheral intravenous ○ PICC line ○ Central intravenous	○ Pre-existing ○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ >5 ○ UNK	○ Yes ○ No	○ Parents objected ○ # of attempts exceeds hospital policy ○ Infant distressed ○ Unable to access vein ○ Reason unknown ○ Other reason		○ Rt Arm ○ Lft Arm ○ Rt Hand ○ Lft Hand ○ Rt Leg ○ Lft Leg ○ Rt Foot ○ Lft Foot ○ Rt side of Neck ○ Lft side of Neck ○ Torso ○ Scalp ○ Other					☐ Not Removed

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 30
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_011_IVIG Infusion - 2.0

Section Title: IVIG Infusion Monitoring

Upload source documents

A1. Was dose administered? *
- ○ Yes
- ○ No

A1a. If No, reason
- ☐ Adverse event
- ☐ Previous dose discontinued
- ☐ IV access lost
- ☐ Caretaker request
- ☐ Other

Other specify

A2. Date dose started | Time dose started | *24 hour clock 0000 format*

A3. Date dose completed or stopped | Time completed or stopped | *24 hour clock 0000 format*

A4. Amount of IVIG in dose (1 gm/kg body weight) gm

A5. Volume of infusion preparation mL

A6. Volume actually infused mL

A7. Was full dose administered?
- ○ Yes
- ○ No

A7a. If No, reason
- ☐ Adverse event
- ☐ IV access lost
- ☐ Caretaker request
- ☐ Other

Other specify

A8. Were there any infusion related adverse events?
- ○ Yes
- ○ No

Day 60:

PRIME_005_Diet - 1.0
PRIME_007_PhysicalExam - 2.0
PRIME_008_Laboratory Results - 4.0
PRIME_009_IV Access Log - 3.0
PRIME_011_IVIG Infusion - 2.0
PRIME_050_Research Lab-Blood - 3.0
PRIME_051_Research Lab-Plasma - 3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_005_Diet - 1.0

Section Title: Diet

A1. What type of diet is the child on? (check all that apply)

- ☐ Human Milk
- ☐ Cow's Milk Based Formula
- ☐ Soy Formula
- ☐ Specialized Formula
- ☐ Parental Nutrition
- ☐ Solid Food
- ☐ Not Specified

A1a. Type of Human Milk

- ☐ Breast Milk
- ☐ Banked Human Milk
- ☐ Not Specified

A1b. Type of Cow's Milk

- ☐ Standard Infant Formula
- ☐ Follow-On Formula
- ☐ Not Specified

A1c. Type of Soy Milk

- ☐ Prosobee
- ☐ Isomil
- ☐ Other Soy Formula — Other Soy, Specify Type
- ☐ Not Specified

A1d. Type of Specialized Milk

- ☐ Alimentum
- ☐ Pregistimil
- ☐ Neocate
- ☐ Low Lactose
- ☐ Nutramigen
- ☐ Other Specialized Formula — Other Specialized, Specify Type
- ☐ Not Specified

A1e. Type of Parental Nutrition

- ☐ Total
- ☐ Partial
- ☐ Not Specified

A2. How is the child fed? (check all that apply)

Indicate Feeding Method

- ☐ Oral
- ☐ Nasogastric
- ☐ Nasoenteric
- ☐ Gastrostomy
- ☐ Gastrojejunostomy
- ☐ Lejunostomy
- ☐ Intravenous
- ☐ Not Specified

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_007_PhysicalExam - 2.0

Section Title: Athropometrics

Upload source documents

A1. Height/Length
(cm) ☐ Not Done

A2. Weight
(kg) ☐ Not Done

A3. Head Circumference
(cm) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Vital Signs

B1. Systolic BP

(mmHg) ☐ Not Done

B2. Diastolic BP

(mmHg) ☐ Not Done

B3. Heart Rate

(beats per min) ☐ Not Done

B4. Respiratory Rate

(breaths per min) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Physical Exam

Skin Exam

C1. Rash *
- ○ Present
- ○ Absent
- ○ Not Done

C1a. If present indicate type
- ☐ Eczema
- ☐ Viral Exanthems
- ☐ Acute Allergic (hives; erythema multiforme)
- ☐ Diaper Rash (candida)
- ☐ Other

If Other Rash, Specify:

C2. Urticaria *
- ○ Present
- ○ Absent
- ○ Not Done

C3. Jaundice *
- ○ Present
- ○ Absent
- ○ Not Done

C3a. If present, indicate location
- ☐ Skin
- ☐ Sclera

C4. Liver Exam *
- ○ Performed
- ○ Not Performed

C4a. Liver Location
- ○ Left Side
- ○ Midline
- ○ Right Side
- ○ Not Palpable
- ○ Not Done

C4b. Liver Span (cm at mid-clavicular line) ND or NP
- ○ Not Done
- ○ Not Palpable

C4c. Liver Edge (cm below costal margin) ND or NP
- ○ Not Done
- ○ Not Palpable

C4d. Liver Edge (cm below xiphoid) ND or NP
- ○ Not Done
- ○ Not Palpable

C4e. Liver Texture
- ○ Soft
- ○ Firm
- ○ Hard
- ○ Nodular and Hard
- ○ Not Palpable

C5. Spleen Exam *
- ○ Performed
- ○ Not Performed

○ Not Palpable

C5a. Spleen Location

○ Left Side
○ Midline
○ Right Side

C5b. Spleen Size (cm below the left (right) costal margin) ☐ Not Done

C6. Ascites
*

○ Present
○ Absent
○ Not Done

C7. Extremities: Peripheral Edema
*

○ Present
○ Absent
○ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_008_Laboratory Results - 4.0

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

Upload Source document file

A1. Total Bilirubin	(mg/dl)	Date	☐ Not Done
A2. Indirect Bilirubin	(mg/dl)	Date	☐ Not Done
A3. Direct Bilirubin	(mg/dl)	Date	☐ Not Done
A4. Unconjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A5. Conjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A6. AST	(U/L)	Date	☐ Not Done
A7. ALT	(U/L)	Date	☐ Not Done
A8. Alkaline Phosphatase	(U/L)	Date	☐ Not Done
A9. GGTP	(U/L)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Coagulation Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

B1. Prothrombin Time (Sec) Date ☐ Not Done

B2. INR Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Basic Metabolic Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

C1. Sodium (Na)	(mmol/l)	Date	☐ Not Done
C2. Potassium (K)	(mmol/l)	Date	☐ Not Done
C3. Chloride (CI)	(mmol/l)	Date	☐ Not Done
C4. Bicarbonate ($CO_{(2)}$)	(mmol/l)	Date	☐ Not Done
C5. Creatinine	(mg/dl)	Date	☐ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: CBC with Differential

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

D1. Hemoglobin (Hgb)	(g/dl) Date		☐ Not Done
D2. Hematocrit (Hct)	(%) Date		☐ Not Done
D3. RBC	(10^3 / mm^3) Date		☐ Not Done
D4. WBC	(10^3 / mm^3) Date		☐ Not Done
D4a. Neutrophils	(%)	☐ Not Done	
D4b. Bands	(%)	☐ Not Done	
D4c. Lymphocytes	(%)	☐ Not Done	
D4d. Monocytes	(%)	☐ Not Done	
D4e. Eosinophils	(%)	☐ Not Done	
D5. Platelets	(10^3 / mm^3) Date		☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Serum IgG

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

E1. Serum Total lgG (mg/dl) Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

A10. Albumin	(g/dL)	Date	☐ Not Done
A11. Total Protein	(g/dL)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_009_IV Access Log - 3.0

Section Title: Venous Access

Instructions: Complete the information requested for each IV access that was used during this infusion.

- If a line was already in place, select pre-existing.
- If IV access was lost during the infusion and was restarted, click ADD to complete the information on the reinserted line.

Select the one best response for each column below:

Upload Source document file

A1. Was an IV Line attempted, inserted, or used for the IVIG infusion at this visit?
*
○ Yes ○ No - End of Form

Which Attempt	Venous Access Type	# of Attempts to Insert IV	Successfully Inserted?	If unsuccessful, why?	If "Other Reason" was selected, Specify below	Location of IV line	Date Attempted/Inserted	Time Inserted	Date Removed	Time Removed	IV Line NOT removed
○ Pre-existing ○ New insertion ○ 1st reinsertion ○ 2nd reinsertion ○ 3rd reinsertion	○ Peripheral intravenous ○ PICC line ○ Central intravenous	○ Pre-existing ○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ >5 ○ UNK	○ Yes ○ No	○ Parents objected ○ # of attempts exceeds hospital policy ○ Infant distressed ○ Unable to access vein ○ Reason unknown ○ Other reason		○ Rt Arm ○ Lft Arm ○ Rt Hand ○ Lft Hand ○ Rt Leg ○ Lft Leg ○ Rt Foot ○ Lft Foot ○ Rt side of Neck ○ Lft side of Neck ○ Torso ○ Scalp ○ Other					☐ Not Removed

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_011_IVIG Infusion - 2.0

Section Title: IVIG Infusion Monitoring

Upload source documents

A1. Was dose administered? *
- ○ Yes
- ○ No

A1a. If No, reason
- ☐ Adverse event
- ☐ Previous dose discontinued
- ☐ IV access lost
- ☐ Caretaker request
- ☐ Other

Other specify

A2. Date dose started | Time dose started | *24 hour clock 0000 format*

A3. Date dose completed or stopped | Time completed or stopped | *24 hour clock 0000 format*

A4. Amount of IVIG in dose (1 gm/kg body weight) gm

A5. Volume of infusion preparation mL

A6. Volume actually infused mL

A7. Was full dose administered?
- ○ Yes
- ○ No

A7a. If No, reason
- ☐ Adverse event
- ☐ IV access lost
- ☐ Caretaker request
- ☐ Other

Other specify

A8. Were there any infusion related adverse events?
- ○ Yes
- ○ No

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_050_Research Lab-Blood - 3.0

Section Title: Research Labs-Whole Blood

A1. Was Whole Blood collected at this visit
* ○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4. Barcode from Whole Blood

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 60
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_051_Research Lab-Plasma - 3.0

Section Title: Plasma Specimens

Whole blood is collected, spun down and the plasma is aliquoted. The aliquots are to be frozen and batch shipped at a later date.
A1. Was Blood collected for plasma at this visit?
* ○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4a. Barcode of Aliquot #1

A4b. Barcode of Aliquot #2

A4c. Barcode of Aliquot #3

A4d. Barcode of Aliquot #4

A4e. Barcode of Aliquot #5

A4f. Barcode of Aliquot #6

Day 90:

PRIME_005_Diet - 1.0
PRIME_007_PhysicalExam - 2.0
PRIME_008_Laboratory Results - 4.0
PRIME_050_Research Lab-Blood - 3.0
PRIME_051_Research Lab-Plasma - 3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_005_Diet - 1.0

Section Title: Diet

A1. What type of diet is the child on? (check all that apply)

- ☐ Human Milk
- ☐ Cow's Milk Based Formula
- ☐ Soy Formula
- ☐ Specialized Formula
- ☐ Parental Nutrition
- ☐ Solid Food
- ☐ Not Specified

A1a. Type of Human Milk

- ☐ Breast Milk
- ☐ Banked Human Milk
- ☐ Not Specified

A1b. Type of Cow's Milk

- ☐ Standard Infant Formula
- ☐ Follow-On Formula
- ☐ Not Specified

A1c. Type of Soy Milk

- ☐ Prosobee
- ☐ Isomil
- ☐ Other Soy Formula — Other Soy, Specify Type
- ☐ Not Specified

A1d. Type of Specialized Milk

- ☐ Alimentum
- ☐ Pregistimil
- ☐ Neocate
- ☐ Low Lactose
- ☐ Nutramigen
- ☐ Other Specialized Formula — Other Specialized, Specify Type
- ☐ Not Specified

A1e. Type of Parental Nutrition

- ☐ Total
- ☐ Partial
- ☐ Not Specified

A2. How is the child fed? (check all that apply)

Indicate Feeding Method

- ☐ Oral
- ☐ Nasogastric
- ☐ Nasoenteric
- ☐ Gastrostomy
- ☐ Gastrojejunostomy
- ☐ Lejunostomy
- ☐ Intravenous
- ☐ Not Specified

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_007_PhysicalExam - 2.0

Section Title: Athropometrics

Upload source documents

A1. Height/Length
(cm) ☐ Not Done

A2. Weight
(kg) ☐ Not Done

A3. Head Circumference
(cm) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Vital Signs

B1. Systolic BP

(mmHg) ☐ Not Done

B2. Diastolic BP

(mmHg) ☐ Not Done

B3. Heart Rate

(beats per min) ☐ Not Done

B4. Respiratory Rate

(breaths per min) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Physical Exam

Skin Exam

C1. Rash *
- ○ Present
- ○ Absent
- ○ Not Done

C1a. If present indicate type
- ☐ Eczema
- ☐ Viral Exanthems
- ☐ Acute Allergic (hives; erythema multiforme)
- ☐ Diaper Rash (candida)
- ☐ Other

If Other Rash, Specify:

C2. Urticaria *
- ○ Present
- ○ Absent
- ○ Not Done

C3. Jaundice *
- ○ Present
- ○ Absent
- ○ Not Done

C3a. If present, indicate location
- ☐ Skin
- ☐ Sclera

C4. Liver Exam *
- ○ Performed
- ○ Not Performed

C4a. Liver Location
- ○ Left Side
- ○ Midline
- ○ Right Side
- ○ Not Palpable
- ○ Not Done

C4b. Liver Span (cm at mid-clavicular line) ND or NP
- ○ Not Done
- ○ Not Palpable

C4c. Liver Edge (cm below costal margin) ND or NP
- ○ Not Done
- ○ Not Palpable

C4d. Liver Edge (cm below xiphoid) ND or NP
- ○ Not Done
- ○ Not Palpable

C4e. Liver Texture
- ○ Soft
- ○ Firm
- ○ Hard
- ○ Nodular and Hard
- ○ Not Palpable

C5. Spleen Exam *
- ○ Performed
- ○ Not Performed

○ Not Palpable

C5a. Spleen Location

○ Left Side
○ Midline
○ Right Side

C5b. Spleen Size (cm below the left (right) costal margin) ☐ Not Done

C6. Ascites
*

○ Present
○ Absent
○ Not Done

C7. Extremities: Peripheral Edema
*

○ Present
○ Absent
○ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_008_Laboratory Results - 4.0

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

Upload Source document file

A1. Total Bilirubin	(mg/dl)	Date	☐ Not Done
A2. Indirect Bilirubin	(mg/dl)	Date	☐ Not Done
A3. Direct Bilirubin	(mg/dl)	Date	☐ Not Done
A4. Unconjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A5. Conjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A6. AST	(U/L)	Date	☐ Not Done
A7. ALT	(U/L)	Date	☐ Not Done
A8. Alkaline Phosphatase	(U/L)	Date	☐ Not Done
A9. GGTP	(U/L)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Coagulation Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

B1. Prothrombin Time (Sec) Date ☐ Not Done

B2. INR Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Basic Metabolic Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

C1. Sodium (Na)	(mmol/l)	Date	☐ Not Done
C2. Potassium (K)	(mmol/l)	Date	☐ Not Done
C3. Chloride (CI)	(mmol/l)	Date	☐ Not Done
C4. Bicarbonate ($CO_{(2)}$)	(mmol/l)	Date	☐ Not Done
C5. Creatinine	(mg/dl)	Date	☐ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: CBC with Differential

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

D1. Hemoglobin (Hgb)	(g/dl) Date		☐ Not Done
D2. Hematocrit (Hct)	(%) Date		☐ Not Done
D3. RBC	(10^3 / mm^3) Date		☐ Not Done
D4. WBC	(10^3 / mm^3) Date		☐ Not Done
D4a. Neutrophils	(%)	☐ Not Done	
D4b. Bands	(%)	☐ Not Done	
D4c. Lymphocytes	(%)	☐ Not Done	
D4d. Monocytes	(%)	☐ Not Done	
D4e. Eosinophils	(%)	☐ Not Done	
D5. Platelets	(10^3 / mm^3) Date		☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Serum IgG

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

E1. Serum Total IgG (mg/dl) Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

A10. Albumin	(g/dL)	Date	☐ Not Done
A11. Total Protein	(g/dL)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_050_Research Lab-Blood - 3.0

Section Title: Research Labs-Whole Blood

A1. Was Whole Blood collected at this visit *
○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4. Barcode from Whole Blood

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 90
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_051_Research Lab-Plasma - 3.0

Section Title: Plasma Specimens

Whole blood is collected, spun down and the plasma is aliquoted. The aliquots are to be frozen and batch shipped at a later date.
A1. Was Blood collected for plasma at this visit?
* ○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4a. Barcode of Aliquot #1

A4b. Barcode of Aliquot #2

A4c. Barcode of Aliquot #3

A4d. Barcode of Aliquot #4

A4e. Barcode of Aliquot #5

A4f. Barcode of Aliquot #6

Day 180:

PRIME_005_Diet - 1.0
PRIME_007_PhysicalExam - 2.0
PRIME_008_Laboratory Results - 4.0
PRIME_050_Research Lab-Blood - 3.0
PRIME_051_Research Lab-Plasma - 3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_005_Diet - 1.0

Section Title: Diet

A1. What type of diet is the child on? (check all that apply)

- ☐ Human Milk
- ☐ Cow's Milk Based Formula
- ☐ Soy Formula
- ☐ Specialized Formula
- ☐ Parental Nutrition
- ☐ Solid Food
- ☐ Not Specified

A1a. Type of Human Milk

- ☐ Breast Milk
- ☐ Banked Human Milk
- ☐ Not Specified

A1b. Type of Cow's Milk

- ☐ Standard Infant Formula
- ☐ Follow-On Formula
- ☐ Not Specified

A1c. Type of Soy Milk

- ☐ Prosobee
- ☐ Isomil
- ☐ Other Soy Formula — Other Soy, Specify Type
- ☐ Not Specified

A1d. Type of Specialized Milk

- ☐ Alimentum
- ☐ Pregistimil
- ☐ Neocate
- ☐ Low Lactose
- ☐ Nutramigen
- ☐ Other Specialized Formula — Other Specialized, Specify Type
- ☐ Not Specified

A1e. Type of Parental Nutrition

- ☐ Total
- ☐ Partial
- ☐ Not Specified

A2. How is the child fed? (check all that apply)

Indicate Feeding Method

- ☐ Oral
- ☐ Nasogastric
- ☐ Nasoenteric
- ☐ Gastrostomy
- ☐ Gastrojejunostomy
- ☐ Lejunostomy
- ☐ Intravenous
- ☐ Not Specified

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_007_PhysicalExam - 2.0

Section Title: Athropometrics

Upload source documents

A1. Height/Length
(cm) ☐ Not Done

A2. Weight
(kg) ☐ Not Done

A3. Head Circumference
(cm) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Vital Signs

B1. Systolic BP

(mmHg) ☐ Not Done

B2. Diastolic BP

(mmHg) ☐ Not Done

B3. Heart Rate

(beats per min) ☐ Not Done

B4. Respiratory Rate

(breaths per min) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Physical Exam

Skin Exam

C1. Rash *
- ○ Present
- ○ Absent
- ○ Not Done

C1a. If present indicate type
- ☐ Eczema
- ☐ Viral Exanthems
- ☐ Acute Allergic (hives; erythema multiforme)
- ☐ Diaper Rash (candida)
- ☐ Other

If Other Rash, Specify:

C2. Urticaria *
- ○ Present
- ○ Absent
- ○ Not Done

C3. Jaundice *
- ○ Present
- ○ Absent
- ○ Not Done

C3a. If present, indicate location
- ☐ Skin
- ☐ Sclera

C4. Liver Exam *
- ○ Performed
- ○ Not Performed

C4a. Liver Location
- ○ Left Side
- ○ Midline
- ○ Right Side
- ○ Not Palpable
- ○ Not Done

C4b. Liver Span (cm at mid-clavicular line) ND or NP
- ○ Not Done
- ○ Not Palpable

C4c. Liver Edge (cm below costal margin) ND or NP
- ○ Not Done
- ○ Not Palpable

C4d. Liver Edge (cm below xiphoid) ND or NP
- ○ Not Done
- ○ Not Palpable

C4e. Liver Texture
- ○ Soft
- ○ Firm
- ○ Hard
- ○ Nodular and Hard
- ○ Not Palpable

C5. Spleen Exam *
- ○ Performed
- ○ Not Performed

○ Not Palpable

C5a. Spleen Location

○ Left Side
○ Midline
○ Right Side

C5b. Spleen Size (cm below the left (right) costal margin) ☐ Not Done

C6. Ascites
*

○ Present
○ Absent
○ Not Done

C7. Extremities: Peripheral Edema
*

○ Present
○ Absent
○ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_008_Laboratory Results - 4.0

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

Upload Source document file

A1. Total Bilirubin	(mg/dl)	Date	☐ Not Done
A2. Indirect Bilirubin	(mg/dl)	Date	☐ Not Done
A3. Direct Bilirubin	(mg/dl)	Date	☐ Not Done
A4. Unconjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A5. Conjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A6. AST	(U/L)	Date	☐ Not Done
A7. ALT	(U/L)	Date	☐ Not Done
A8. Alkaline Phosphatase	(U/L)	Date	☐ Not Done
A9. GGTP	(U/L)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Coagulation Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

B1. Prothrombin Time (Sec) Date ☐ Not Done

B2. INR Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Basic Metabolic Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

C1. Sodium (Na)	(mmol/l)	Date	☐ Not Done
C2. Potassium (K)	(mmol/l)	Date	☐ Not Done
C3. Chloride (CI)	(mmol/l)	Date	☐ Not Done
C4. Bicarbonate ($CO_{(2)}$)	(mmol/l)	Date	☐ Not Done
C5. Creatinine	(mg/dl)	Date	☐ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: CBC with Differential

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

D1. Hemoglobin (Hgb)	(g/dl) Date		☐ Not Done
D2. Hematocrit (Hct)	(%) Date		☐ Not Done
D3. RBC	(10^3 / mm^3) Date		☐ Not Done
D4. WBC	(10^3 / mm^3) Date		☐ Not Done
D4a. Neutrophils	(%)	☐ Not Done	
D4b. Bands	(%)	☐ Not Done	
D4c. Lymphocytes	(%)	☐ Not Done	
D4d. Monocytes	(%)	☐ Not Done	
D4e. Eosinophils	(%)	☐ Not Done	
D5. Platelets	(10^3 / mm^3) Date		☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Serum IgG

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

E1. Serum Total IgG (mg/dl) Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

A10. Albumin	(g/dL)	Date	☐ Not Done
A11. Total Protein	(g/dL)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_050_Research Lab-Blood - 3.0

Section Title: Research Labs-Whole Blood

A1. Was Whole Blood collected at this visit *
○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4. Barcode from Whole Blood

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 180
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_051_Research Lab-Plasma - 3.0

Section Title: Plasma Specimens

Whole blood is collected, spun down and the plasma is aliquoted. The aliquots are to be frozen and batch shipped at a later date.
A1. Was Blood collected for plasma at this visit?
* ○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4a. Barcode of Aliquot #1

A4b. Barcode of Aliquot #2

A4c. Barcode of Aliquot #3

A4d. Barcode of Aliquot #4

A4e. Barcode of Aliquot #5

A4f. Barcode of Aliquot #6

Day 270:

PRIME_005_Diet - 1.0
PRIME_007_PhysicalExam - 2.0
PRIME_008_Laboratory Results - 4.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 270
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_005_Diet - 1.0

Section Title: Diet

A1. What type of diet is the child on? (check all that apply)

- ☐ Human Milk
- ☐ Cow's Milk Based Formula
- ☐ Soy Formula
- ☐ Specialized Formula
- ☐ Parental Nutrition
- ☐ Solid Food
- ☐ Not Specified

A1a. Type of Human Milk

- ☐ Breast Milk
- ☐ Banked Human Milk
- ☐ Not Specified

A1b. Type of Cow's Milk

- ☐ Standard Infant Formula
- ☐ Follow-On Formula
- ☐ Not Specified

A1c. Type of Soy Milk

- ☐ Prosobee
- ☐ Isomil
- ☐ Other Soy Formula — Other Soy, Specify Type
- ☐ Not Specified

A1d. Type of Specialized Milk

- ☐ Alimentum
- ☐ Pregistimil
- ☐ Neocate
- ☐ Low Lactose
- ☐ Nutramigen
- ☐ Other Specialized Formula — Other Specialized, Specify Type
- ☐ Not Specified

A1e. Type of Parental Nutrition

- ☐ Total
- ☐ Partial
- ☐ Not Specified

A2. How is the child fed? (check all that apply)

Indicate Feeding Method

- ☐ Oral
- ☐ Nasogastric
- ☐ Nasoenteric
- ☐ Gastrostomy
- ☐ Gastrojejunostomy
- ☐ Lejunostomy
- ☐ Intravenous
- ☐ Not Specified

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 270
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_007_PhysicalExam - 2.0

Section Title: Athropometrics

Upload source documents

A1. Height/Length
(cm) ☐ Not Done

A2. Weight
(kg) ☐ Not Done

A3. Head Circumference
(cm) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 270
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Vital Signs

B1. Systolic BP

(mmHg) ☐ Not Done

B2. Diastolic BP

(mmHg) ☐ Not Done

B3. Heart Rate

(beats per min) ☐ Not Done

B4. Respiratory Rate

(breaths per min) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 270
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Physical Exam

Skin Exam

C1. Rash *
- ○ Present
- ○ Absent
- ○ Not Done

C1a. If present indicate type
- ☐ Eczema
- ☐ Viral Exanthems
- ☐ Acute Allergic (hives; erythema multiforme)
- ☐ Diaper Rash (candida)
- ☐ Other

If Other Rash, Specify:

C2. Urticaria *
- ○ Present
- ○ Absent
- ○ Not Done

C3. Jaundice *
- ○ Present
- ○ Absent
- ○ Not Done

C3a. If present, indicate location
- ☐ Skin
- ☐ Sclera

C4. Liver Exam *
- ○ Performed
- ○ Not Performed

C4a. Liver Location
- ○ Left Side
- ○ Midline
- ○ Right Side
- ○ Not Palpable
- ○ Not Done

C4b. Liver Span (cm at mid-clavicular line) ND or NP
- ○ Not Done
- ○ Not Palpable

C4c. Liver Edge (cm below costal margin) ND or NP
- ○ Not Done
- ○ Not Palpable

C4d. Liver Edge (cm below xiphoid) ND or NP
- ○ Not Done
- ○ Not Palpable

C4e. Liver Texture
- ○ Soft
- ○ Firm
- ○ Hard
- ○ Nodular and Hard
- ○ Not Palpable

C5. Spleen Exam *
- ○ Performed
- ○ Not Performed

○ Not Palpable

C5a. Spleen Location

○ Left Side
○ Midline
○ Right Side

C5b. Spleen Size (cm below the left (right) costal margin) ☐ Not Done

C6. Ascites
*

○ Present
○ Absent
○ Not Done

C7. Extremities: Peripheral Edema
*

○ Present
○ Absent
○ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 270
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_008_Laboratory Results - 4.0

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

Upload Source document file

A1. Total Bilirubin	(mg/dl)	Date	☐ Not Done
A2. Indirect Bilirubin	(mg/dl)	Date	☐ Not Done
A3. Direct Bilirubin	(mg/dl)	Date	☐ Not Done
A4. Unconjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A5. Conjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A6. AST	(U/L)	Date	☐ Not Done
A7. ALT	(U/L)	Date	☐ Not Done
A8. Alkaline Phosphatase	(U/L)	Date	☐ Not Done
A9. GGTP	(U/L)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 270
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Coagulation Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

B1. Prothrombin Time (Sec) Date ☐ Not Done

B2. INR Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 270
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Basic Metabolic Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

C1. Sodium (Na)	(mmol/l)	Date	☐ Not Done
C2. Potassium (K)	(mmol/l)	Date	☐ Not Done
C3. Chloride (CI)	(mmol/l)	Date	☐ Not Done
C4. Bicarbonate ($CO_{(2)}$)	(mmol/l)	Date	☐ Not Done
C5. Creatinine	(mg/dl)	Date	☐ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 270
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: CBC with Differential

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

D1. Hemoglobin (Hgb)	(g/dl) Date		☐ Not Done
D2. Hematocrit (Hct)	(%) Date		☐ Not Done
D3. RBC	(10^3 / mm^3) Date		☐ Not Done
D4. WBC	(10^3 / mm^3) Date		☐ Not Done
D4a. Neutrophils	(%)	☐ Not Done	
D4b. Bands	(%)	☐ Not Done	
D4c. Lymphocytes	(%)	☐ Not Done	
D4d. Monocytes	(%)	☐ Not Done	
D4e. Eosinophils	(%)	☐ Not Done	
D5. Platelets	(10^3 / mm^3) Date		☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 270
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Serum IgG

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

E1. Serum Total lgG (mg/dl) Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 270
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Hepatic Function Panel
Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

A10. Albumin	(g/dL)	Date	☐ Not Done
A11. Total Protein	(g/dL)	Date	☐ Not Done

Day 360:

PRIME_005_Diet - 1.0
PRIME_007_PhysicalExam - 2.0
PRIME_008_Laboratory Results - 4.0
PRIME_050_Research Lab-Blood - 3.0
PRIME_051_Research Lab-Plasma - 3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_005_Diet - 1.0

Section Title: Diet

A1. What type of diet is the child on? (check all that apply)

- ☐ Human Milk
- ☐ Cow's Milk Based Formula
- ☐ Soy Formula
- ☐ Specialized Formula
- ☐ Parental Nutrition
- ☐ Solid Food
- ☐ Not Specified

A1a. Type of Human Milk

- ☐ Breast Milk
- ☐ Banked Human Milk
- ☐ Not Specified

A1b. Type of Cow's Milk

- ☐ Standard Infant Formula
- ☐ Follow-On Formula
- ☐ Not Specified

A1c. Type of Soy Milk

- ☐ Prosobee
- ☐ Isomil
- ☐ Other Soy Formula — Other Soy, Specify Type
- ☐ Not Specified

A1d. Type of Specialized Milk

- ☐ Alimentum
- ☐ Pregistimil
- ☐ Neocate
- ☐ Low Lactose
- ☐ Nutramigen
- ☐ Other Specialized Formula — Other Specialized, Specify Type
- ☐ Not Specified

A1e. Type of Parental Nutrition

- ☐ Total
- ☐ Partial
- ☐ Not Specified

A2. How is the child fed? (check all that apply)

Indicate Feeding Method

- ☐ Oral
- ☐ Nasogastric
- ☐ Nasoenteric
- ☐ Gastrostomy
- ☐ Gastrojejunostomy
- ☐ Lejunostomy
- ☐ Intravenous
- ☐ Not Specified

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_007_PhysicalExam - 2.0

Section Title: Athropometrics

Upload source documents

A1. Height/Length
(cm) ☐ Not Done

A2. Weight
(kg) ☐ Not Done

A3. Head Circumference
(cm) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Vital Signs

B1. Systolic BP

(mmHg) ☐ Not Done

B2. Diastolic BP

(mmHg) ☐ Not Done

B3. Heart Rate

(beats per min) ☐ Not Done

B4. Respiratory Rate

(breaths per min) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Physical Exam

Skin Exam

C1. Rash *
- ○ Present
- ○ Absent
- ○ Not Done

C1a. If present indicate type
- ☐ Eczema
- ☐ Viral Exanthems
- ☐ Acute Allergic (hives; erythema multiforme)
- ☐ Diaper Rash (candida)
- ☐ Other

If Other Rash, Specify:

C2. Urticaria *
- ○ Present
- ○ Absent
- ○ Not Done

C3. Jaundice *
- ○ Present
- ○ Absent
- ○ Not Done

C3a. If present, indicate location
- ☐ Skin
- ☐ Sclera

C4. Liver Exam *
- ○ Performed
- ○ Not Performed

C4a. Liver Location
- ○ Left Side
- ○ Midline
- ○ Right Side
- ○ Not Palpable
- ○ Not Done

C4b. Liver Span (cm at mid-clavicular line) ND or NP
- ○ Not Done
- ○ Not Palpable

C4c. Liver Edge (cm below costal margin) ND or NP
- ○ Not Done
- ○ Not Palpable

C4d. Liver Edge (cm below xiphoid) ND or NP
- ○ Not Done
- ○ Not Palpable

C4e. Liver Texture
- ○ Soft
- ○ Firm
- ○ Hard
- ○ Nodular and Hard
- ○ Not Palpable

C5. Spleen Exam *
- ○ Performed
- ○ Not Performed

○ Not Palpable

C5a. Spleen Location

○ Left Side
○ Midline
○ Right Side

C5b. Spleen Size (cm below the left (right) costal margin) ☐ Not Done

C6. Ascites
*

○ Present
○ Absent
○ Not Done

C7. Extremities: Peripheral Edema
*

○ Present
○ Absent
○ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_008_Laboratory Results - 4.0

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

Upload Source document file

A1. Total Bilirubin	(mg/dl)	Date	☐ Not Done
A2. Indirect Bilirubin	(mg/dl)	Date	☐ Not Done
A3. Direct Bilirubin	(mg/dl)	Date	☐ Not Done
A4. Unconjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A5. Conjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A6. AST	(U/L)	Date	☐ Not Done
A7. ALT	(U/L)	Date	☐ Not Done
A8. Alkaline Phosphatase	(U/L)	Date	☐ Not Done
A9. GGTP	(U/L)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Coagulation Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

B1. Prothrombin Time (Sec) Date ☐ Not Done

B2. INR Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Basic Metabolic Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

C1. Sodium (Na)	(mmol/l)	Date	☐ Not Done
C2. Potassium (K)	(mmol/l)	Date	☐ Not Done
C3. Chloride (CI)	(mmol/l)	Date	☐ Not Done
C4. Bicarbonate ($CO_{(2)}$)	(mmol/l)	Date	☐ Not Done
C5. Creatinine	(mg/dl)	Date	☐ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: CBC with Differential

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

D1. Hemoglobin (Hgb)	(g/dl) Date		☐ Not Done
D2. Hematocrit (Hct)	(%) Date		☐ Not Done
D3. RBC	(10^3 / mm^3) Date		☐ Not Done
D4. WBC	(10^3 / mm^3) Date		☐ Not Done
D4a. Neutrophils	(%)	☐ Not Done	
D4b. Bands	(%)	☐ Not Done	
D4c. Lymphocytes	(%)	☐ Not Done	
D4d. Monocytes	(%)	☐ Not Done	
D4e. Eosinophils	(%)	☐ Not Done	
D5. Platelets	(10^3 / mm^3) Date		☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Serum IgG

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

E1. Serum Total lgG (mg/dl) Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

A10. Albumin	(g/dL)	Date	☐ Not Done
A11. Total Protein	(g/dL)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_050_Research Lab-Blood - 3.0

Section Title: Research Labs-Whole Blood

A1. Was Whole Blood collected at this visit
* ○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4. Barcode from Whole Blood

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Day 360
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_051_Research Lab-Plasma - 3.0

Section Title: Plasma Specimens

Whole blood is collected, spun down and the plasma is aliquoted. The aliquots are to be frozen and batch shipped at a later date.
A1. Was Blood collected for plasma at this visit?
* ○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4a. Barcode of Aliquot #1

A4b. Barcode of Aliquot #2

A4c. Barcode of Aliquot #3

A4d. Barcode of Aliquot #4

A4e. Barcode of Aliquot #5

A4f. Barcode of Aliquot #6

Transplant:

PRIME_005_Diet - 1.0
PRIME_007_PhysicalExam - 2.0
PRIME_008_Laboratory Results - 4.0
PRIME_025_Transplant - 2.0
PRIME_050_Research Lab-Blood - 2.0
PRIME_051_Research Lab-Plasma - 2.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_005_Diet - 1.0

Section Title: Diet

A1. What type of diet is the child on? (check all that apply)

- ☐ Human Milk
- ☐ Cow's Milk Based Formula
- ☐ Soy Formula
- ☐ Specialized Formula
- ☐ Parental Nutrition
- ☐ Solid Food
- ☐ Not Specified

A1a. Type of Human Milk

- ☐ Breast Milk
- ☐ Banked Human Milk
- ☐ Not Specified

A1b. Type of Cow's Milk

- ☐ Standard Infant Formula
- ☐ Follow-On Formula
- ☐ Not Specified

A1c. Type of Soy Milk

- ☐ Prosobee
- ☐ Isomil
- ☐ Other Soy Formula — Other Soy, Specify Type
- ☐ Not Specified

A1d. Type of Specialized Milk

- ☐ Alimentum
- ☐ Pregistimil
- ☐ Neocate
- ☐ Low Lactose
- ☐ Nutramigen
- ☐ Other Specialized Formula — Other Specialized, Specify Type
- ☐ Not Specified

A1e. Type of Parental Nutrition

- ☐ Total
- ☐ Partial
- ☐ Not Specified

A2. How is the child fed? (check all that apply)

Indicate Feeding Method

- ☐ Oral
- ☐ Nasogastric
- ☐ Nasoenteric
- ☐ Gastrostomy
- ☐ Gastrojejunostomy
- ☐ Lejunostomy
- ☐ Intravenous
- ☐ Not Specified

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_007_PhysicalExam - 2.0

Section Title: Athropometrics

Upload source documents

A1. Height/Length
(cm) ☐ Not Done

A2. Weight
(kg) ☐ Not Done

A3. Head Circumference
(cm) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Vital Signs

B1. Systolic BP

(mmHg) ☐ Not Done

B2. Diastolic BP

(mmHg) ☐ Not Done

B3. Heart Rate

(beats per min) ☐ Not Done

B4. Respiratory Rate

(breaths per min) ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Physical Exam

Skin Exam

C1. Rash *
- ○ Present
- ○ Absent
- ○ Not Done

C1a. If present indicate type
- ☐ Eczema
- ☐ Viral Exanthems
- ☐ Acute Allergic (hives; erythema multiforme)
- ☐ Diaper Rash (candida)
- ☐ Other

If Other Rash, Specify:

C2. Urticaria *
- ○ Present
- ○ Absent
- ○ Not Done

C3. Jaundice *
- ○ Present
- ○ Absent
- ○ Not Done

C3a. If present, indicate location
- ☐ Skin
- ☐ Sclera

C4. Liver Exam *
- ○ Performed
- ○ Not Performed

C4a. Liver Location
- ○ Left Side
- ○ Midline
- ○ Right Side
- ○ Not Palpable
- ○ Not Done

C4b. Liver Span (cm at mid-clavicular line) ND or NP
- ○ Not Done
- ○ Not Palpable

C4c. Liver Edge (cm below costal margin) ND or NP
- ○ Not Done
- ○ Not Palpable

C4d. Liver Edge (cm below xiphoid) ND or NP
- ○ Not Done
- ○ Not Palpable

C4e. Liver Texture
- ○ Soft
- ○ Firm
- ○ Hard
- ○ Nodular and Hard
- ○ Not Palpable

C5. Spleen Exam *
- ○ Performed
- ○ Not Performed

○ Not Palpable

C5a. Spleen Location

○ Left Side
○ Midline
○ Right Side

C5b. Spleen Size (cm below the left (right) costal margin) ☐ Not Done

C6. Ascites
*

○ Present
○ Absent
○ Not Done

C7. Extremities: Peripheral Edema
*

○ Present
○ Absent
○ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_008_Laboratory Results - 4.0

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

Upload Source document file

A1. Total Bilirubin	(mg/dl)	Date	☐ Not Done
A2. Indirect Bilirubin	(mg/dl)	Date	☐ Not Done
A3. Direct Bilirubin	(mg/dl)	Date	☐ Not Done
A4. Unconjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A5. Conjugated Bilirubin	(mg/dl)	Date	☐ Not Done
A6. AST	(U/L)	Date	☐ Not Done
A7. ALT	(U/L)	Date	☐ Not Done
A8. Alkaline Phosphatase	(U/L)	Date	☐ Not Done
A9. GGTP	(U/L)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Coagulation Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

B1. Prothrombin Time (Sec) Date ☐ Not Done

B2. INR Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Basic Metabolic Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

C1. Sodium (Na)	(mmol/l)	Date	☐ Not Done
C2. Potassium (K)	(mmol/l)	Date	☐ Not Done
C3. Chloride (CI)	(mmol/l)	Date	☐ Not Done
C4. Bicarbonate ($CO_{(2)}$)	(mmol/l)	Date	☐ Not Done
C5. Creatinine	(mg/dl)	Date	☐ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: CBC with Differential

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

D1. Hemoglobin (Hgb)	(g/dl) Date		☐ Not Done
D2. Hematocrit (Hct)	(%) Date		☐ Not Done
D3. RBC	(10^3 / mm^3) Date		☐ Not Done
D4. WBC	(10^3 / mm^3) Date		☐ Not Done
D4a. Neutrophils	(%)	☐ Not Done	
D4b. Bands	(%)	☐ Not Done	
D4c. Lymphocytes	(%)	☐ Not Done	
D4d. Monocytes	(%)	☐ Not Done	
D4e. Eosinophils	(%)	☐ Not Done	
D5. Platelets	(10^3 / mm^3) Date		☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Serum IgG

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

E1. Serum Total lgG (mg/dl) Date ☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Hepatic Function Panel

Instructions: **If a lab is reported as below lower limit of detection then enter as LL. If a lab is reported as above the upper limit of detection then enter as UL. A < or > sign is acceptable for certain labs if it is reported as such.**

A10. Albumin	(g/dL)	Date	☐ Not Done
A11. Total Protein	(g/dL)	Date	☐ Not Done

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_025_Transplant - 2.0

Section Title: Transplant

A1. Date of Transplant
*

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: PELD Scores

B1. Calculated

B2. Exception

☐ Not Done

B3. Status 1 exception

○ Not Requested
○ Requested

B4. Growth Failure (weight or length more than two standard deviations below normal)

○ Yes
○ No

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Donor Information

C1. Donor Type

- ○ Cadaveric
- ○ Living related donor
- ○ Living unrelated donor

C1a. If cadaveric, which type

- ○ Unknown
- ○ Whole
- ○ Reduces
- ○ Split

C2. Donor Age

Years or Months

- ○ Years
- ○ Months

☐ Missing

C3. Donor Gender

- ○ Missing
- ○ Male
- ○ Female

kg

☐ Missing

C5. Donor Blood Type

- ○ Missing
- ○ A
- ○ B
- ○ O
- ○ AB

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

Section Title: Complications

D1. Complications present or actively treated at time of transplant
(check all that apply)

- ☐ None
- ☐ Failure to thrive
- ☐ Ascites
- ☐ Cholangitis
- ☐ Failed hepatoportoenterostomy
- ☐ Coagulopathy
- ☐ Varices
- ☐ GI bleed
- ☐ Encephalopathy
- ☐ Hepatopulmonary syndrome
- ☐ Hepatorenal syndrome
- ☐ No information available
- ☐ Other

If other, specify

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_050_Research Lab-Blood - 2.0

Section Title: Research Labs-Whole Blood

A1. Was Whole Blood collected at this visit *
○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4. Barcode from Whole Blood

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Transplant
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_051_Research Lab-Plasma - 2.0

Section Title: Plasma Specimens

Whole blood is collected, spun down and the plasma is aliquoted. The aliquots are to be frozen and batch shipped at a later date.
A1. Was Blood collected for plasma at this visit?
*

○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4a. Barcode of Aliquot #1

A4b. Barcode of Aliquot #2

A4c. Barcode of Aliquot #3

A4d. Barcode of Aliquot #4

A4e. Barcode of Aliquot #5

A4f. Barcode of Aliquot #6

AE/Med/Deviation Logs:

PRIME_013_Concomitant Medications - 6.0
PRIME_020_Adverses Event Log - 3
PRIME_040_Protocol Deviation Log - 3

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: AE/Med/Deviation Logs
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_013_Concomitant Medications - 6.0

Section Title: Concomitant Medications

Instructions:
For each row below, select one Medication from the list, or select "Other" and Specify the Medication in the field provided.
Select just one Unit and Frequency for each row entered.
Start and Stop Dates must be complete. (If day of the month is unknown, please provide an accurate estimate of that day.)

Medication Name	If Other was selected, List Medication Name	Total Daily Dose		Dose Units	Frequency	Indication	Start Date	Stop Date	
○ Acetaminophen ○ Actigall ○ Amoxicillin ○ Augmentin ○ Antihistamines ○ AquaDEK ○ Bactrim ○ Benedryl ○ Branch chain amino acids ○ Calcium ○ Clotrimazole anti-fungal cream ○ Cholestyramine (e.g. Questran) ○ Desitin diaper rash cream ○ Diphenhydramine ○ Duocal ○ Furosemide (e.g. Lasix) ○ Hydrocortisone 1% cream ○ Medium chain triglycerids (MCT) oil ○ Mephyton ○ Methylprednisolone ○ Multivitamin ○ Neomycin ○ Nystatin ○ Polycose ○ Prednisolone ○ Prednisone ○ Rifampin ○ Solu-Medrol ○ Spironolactone (e.g. Aldactone) ○ Trimethoprim/sulfamethoxazole ○ Ursodeoxycholic acid ○ Vitamin A ○ Vitamin C ○ Vitamin D ○ Vitamin E ○ Vitamin K ○ Zinc oxide cream ○ D5W(Dextrose 5% in water) ○ D5NS ○ D5 1/2NS ○ NaCl 0.9% ○ KCl ○ Ranitidine ○ Cefotaxime ○ Ciprofloxacin ○ Fluconazole ○ Oxycodone ○ Vaccine H Influenza B ○ Vaccine pneumoccocal			☐ Unknown	○ mg ○ G ○ gtt ○ ml ○ mEq ○ cc ○ drops ○ puffs ○ tabs ○ IU ○ Application ○ Unknown	○ Once ○ QD ○ BID ○ TID ○ QID ○ PRN ○ EOD ○ QW ○ 1/month ○ 3/week ○ q 4 hr ○ q 6 hr ○ q 12 hr ○ Unknown				☐ Ongoing

○ Vaccine DTAP ○ Vaccine Hep B ○ Vaccine inactivated polio ○ Vaccine Rotavirus ○ Vaccine Hep A ○ Vaccine MMR ○ Vancomycin ○ Zosyn ○ Other									

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: AE/Med/Deviation Logs
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_020_Adverses Event Log - 3

Section Title: Adverse Events

Subtitle: If an Event is Serious, enter on Form 45 instead of this Log.
Please use the Common Terminology Criteria for Adverse Events (CTCAE) link on the ChiLDREN Website when Specifying the event and Severity grading.

Instructions:

1. **Adverse Event:** Choose an event from the drop down list. Enter one event per line. If the event is not in the list, choose Other, and Specify in the next column.
2. **Onset Date:** Enter the date the Adverse Event Began. If complete date is unknown, enter an estimate. Partial dates are not accepted.
3. **Resolution Date:** Enter the date the Adverse Event ended. If complete date is unknown, enter an estimate. Partial dates are not accepted. (If the AE is ongoing, leave this field blank.) When AE has ended, update this field with the AE end date.
4. **Severity:** Indicate the severity grade of the AE. For accurate grading, refer to "Common Terminology Criteria for Adverse Events" .
5. **Expected or Unexpected:** Indicate if this is an expected adverse event, as outlined in the protocol.
6. **Relationship to IVIG, TMP-SMZ, Urso:** For each study medication, indicate if it had a causal effect on that Adverse Event, as reported by the Clinician/Investigator.
7. **Did AE occur during IVIG infusion?:** The AE occurred during the IVIG infusion period, if it occurred during IV insertion, during infusion, or directly after infusion.
8. **Action Taken regarding Study Drug:** Indicate the action taken with IVIG in response to the AE. (Report action taken for Urso and TMP-SMZ, dose change or discontinued, on Form 013 Concomitant Medications.)
9. **Outcome:** Indicate the outcome of the event.
10. **Treatment Required:** Indicate if medication or other treatment was required to treat this event. (If yes, enter details on Form 13 Concomitant Medication Log.)

Select one response for each field.

Were any Adverse Events experienced? *
○ Yes
○ No

Adverse Event:	Specify, if Other	Onset Date	Resolution Date	Severity:	Expected or Unexpected	Relationship to IVIG	Relationship to TMP-SMZ	Relationship to Urso	Did AE occur during IVIG infusion	Action taken regarding IVIG	Outcome:	Treatment required
○ Other ○ Acholic Stools ○ Allergic reaction ○ Allergic rhinitis ○ Anemia ○ Ascites ○ Biliary tract infection ○ Bladder infection ○ Bronchial infection ○ IV Catheter-related infection ○ Cold Symptoms ○ Congestion ○ Constipation ○ Cough ○ Creatinine increased ○ Decreased Feeding ○ Dehydration ○ Diarrhea ○ Diaper Rash ○ Difficulty breathing ○ Eczema ○ Edema ○ Elevated Bilirubin ○ Elevated INR ○ Elevated Transaminases				○ Grade 1 Mild ○ Grade 2 Moderate ○ Grade 3 Severe	○ Expected ○ Unexpected	○ Not Assessible ○ Unlikely ○ Possible ○ Probable ○ Definite	○ Not Assessible ○ Unlikely ○ Possible ○ Probable ○ Definite	○ Not Assessible ○ Unlikely ○ Possible ○ Probable ○ Definite	○ Yes ○ No	○ None ○ Infusion rate decreased ○ Infusion interrupted ○ IVIG Discontinued ○ Unknown	○ Recovered ○ Recovered with sequelae ○ Ongoing ○ Unknown	○ Yes ○ No ○ Unknown

○ Elevation In AST & ALT ○ Elevation in systolic blood pressure >112mmHG ○ Emesis ○ Epistaxis ○ Failure to Thrive ○ Feeding Intolerance ○ Fever ○ Flu-like symptoms ○ Fussiness ○ Gastrointestinal disorder ○ Headache ○ Hypertension ○ Hypoalbuminemia ○ Hypocalcemia ○ Hypotension ○ Hypothroidism ○ Inadequate Weight Gain ○ Increased PT/INR ○ Increased Sleepiness ○ Influenza A ○ Infusion site extravasation ○ Irritability ○ Infusion related reaction ○ Jaundice ○ Jaundice – sceral ○ Jaundice – skin ○ Leukocytosis ○ Localized edema ○ Edema-limbs ○ Low Iron ○ Neutropenia ○ Nasal congestion ○ Oral Thrush ○ Otitis externa ○ Otitis media ○ Poor Nutritional Status ○ Poor Weight Gain ○ Pruritis ○ Rash ○ Reflux ○ Roseola ○ RSV ○ Sinus Infection ○ Skin infection ○ Sore Throat ○ Strep Pharyngitis ○ Tinea Capitis-Ringworm ○ Upper Respiratory Infection ○ Urinary tract infection ○ Urticaria ○ Viral Illness ○ Vomiting ○ Weight Loss ○ Wheezing												

Study Name: PRIME
Site: _____
Event Name: AE/Med/Deviation Logs
Event Date: _____

Interviewer Name:_____

PRIME_040_Protocol Deviation Log - 3

Section Title: Protocol Deviation

Instructions:
Select Only One response for each field.

Were there any deviations for this subject?
* ○ yes ○ no

Which Visit?	Deviation	If Other deviation, specify	If Study Procedure, which one	Reason	Additional Comments
○ Not visit related ○ Enrollment ○ Day 3-5 ○ Day 14 ○ Day 30 ○ Day 60 ○ Day 90 ○ Day 180 ○ Day 270 ○ Day 360 ○ Transplant	○ Missed visit ○ Informed Consent deviation ○ Study procedure not completed ○ IVIG not given ○ IVIG dose error ○ TMP-SMZ dose error ○ ursodiol dose error ○ Out of Window ○ Other		○ Vitals ○ Anthropometrics ○ Physical Exam ○ Con meds assessment ○ Diet assessment ○ Clinical Lab ○ Research Lab ○ Other	○ Site error ○ Subject refused ○ Subject too ill ○ Time constraints ○ Other ○ Unknown	

SAE:

PRIME_045_SAE-Serious Adverse Event - 6.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: SAE
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_045_SAE-Serious Adverse Event - 6.0

Section Title: Serious Adverse Event

Instructions: This form will be completed for all SAEs regardless of expectedness or relatedness

A0. Has the subject had a liver transplant?
*
- ○ Yes
- ○ No

A0a. Date of Transplant (DD-MMM-YYYY)

A1. AE Diagnosis
*

A2. AE Description

A2a. Subject's weight at time of SAE? (kg)

A2b. Subject's age at time of SAE (months)

A3. Specify Treatment

A4. SAE Start Date
* (DD-MMM-YYYY) TIME: (0000 24 hour clock)

A5. Outcome of SAE
*
- ○ Recovered/resolved
- ○ Recovering/resolving
- ○ Not recovered/not resolved
- ○ Recovered/resolved w. sequelae
- ○ Fatal
- ○ Unknown

A5a. End Date (DD-MMM-YYYY) TIME: (0000 24 hour clock)

A6. Indicate Severity of SAE *(Refer to CTCAE criteria for definitions).*
- ○ Grade 1 Mild
- ○ Grade 2 Moderate
- ○ Grade 3 Severe
- ○ Grade 4 Life-threatening or disabling AE
- ○ Grade 5 Death related to AE

A7. Causality of SAE (relationship to Study medications)
*
- ○ Definite*
- ○ Probable*
- ○ Possible*
- ○ Unlikely
- ○ Not assessable

*A7a. If causality is Definite, Probable or Possible indicate causal medication(s)
- ☐ IVIG
- ☐ TMP-SMZ
- ☐ Ursodeoxycholic acid
- ☐ Unknown

A8. Was event Expected or Unexpected: *Refer to MOO for list of expected events*
*
- ○ Expected

○ Unexpected

A9. Was AE serious?
*
○ Yes
○ No

A9a. If Yes, please check all that apply ☐ Fatal

☐ Congenital Abnormality

☐ Hospitalization intial or prolonged
☐ Hospitalization initial or prolonged

☐ Required intervention to prevent permanent impairment/damage

☐ Life-threatening

☐ Significant Disability

☐ Other If Other, Specify:

A10. Date of last IVIG Dose
(DD-MMM-YYYY)

A11. Action Taken with IVIG due to this event
☐ None

☐ Infusion rate decreased

☐ Infusion interrupted

☐ IVIG Discontinued

A11a. Did AE abate after IVIG stopped or rate reduced?
○ Yes
○ No
○ Not Applicable

A12. Upload final SAE summary here

A13. Upload Source document

Final Status:

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Final Status
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_035_Final Status - 1.0

Section Title: Final Status

A0. Final Status Effective Date
*

A1. What is the Subject's Final Status?
*
- ○ Completed study
- ○ Ineligible
- ○ Investigator withdrew subject
- ○ Subject voluntarily withdrew
- ○ Lost to Follow-up
- ○ Subject no longer being followed at a ChiLDREN site
- ○ Study terminated by sponsor
- ○ Death
- ○ Subject transferred
- ○ Other

Other Reason: Specify

A1a. Reason PI withdrew Subject
- ☐ Medical concern
- ☐ Not compliant
- ☐ Other Other Reason: Specify

A1b. Reason Subject voluntarily withdrew
- ☐ Study procedures were not acceptable
- ☐ Unable to adhere to visit schedule
- ☐ Adverse event
- ☐ Lack of Efficacy
- ☐ Other Other Reason: Specify

A1c. Which study procedure was not acceptable?
- ○ IV line insertion Other Reason: Specify
- ○ Blood draws
- ○ Other

A1d. Transferred to Site#:

A1e. New Subject ID#:

Unscheduled:

PRIME_050_Research Lab-Blood - 3.0
PRIME_051_Research Lab-Plasma - 3.0

Investigator Name: _____ Investigator Signature: _____ Date: _____

Protocol ID: P007
Study Name: PRIME
Study Subject ID:_____
Interviewer Name:_____

Site: _____
Event Name: Unscheduled
Event Date: _____

PRIME_050_Research Lab-Blood - 3.0

Section Title: Research Labs-Whole Blood

A1. Was Whole Blood collected at this visit *
○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4. Barcode from Whole Blood

Protocol ID: P007
Study Name: PRIME
Site: _____
Event Name: Unscheduled
Event Date: _____

Study Subject ID:_____
Interviewer Name:_____

PRIME_051_Research Lab-Plasma - 3.0

Section Title: Plasma Specimens

Whole blood is collected, spun down and the plasma is aliquoted. The aliquots are to be frozen and batch shipped at a later date.
A1. Was Blood collected for plasma at this visit?
*

○ Yes ○ No

A2. Date Collected *DD-MMM-YYYY*

A3. Date Shipped *DD-MMM-YYYY*

A4a. Barcode of Aliquot #1

A4b. Barcode of Aliquot #2

A4c. Barcode of Aliquot #3

A4d. Barcode of Aliquot #4

A4e. Barcode of Aliquot #5

A4f. Barcode of Aliquot #6