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

	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	Х												
PRIME_001_Eligibility - 1.0	Х												
PRIME_015_Exemption Request - 1.0	Х												
PRIME_005_Diet - 1.0		Х	Х	Х	Х	Х	Х	Х	Х	Х			
PRIME_007_PhysicalExam - 2.0		Х	Х	Х	Х	Х	Х	Х	Х	Х			
PRIME_008_Laboratory Results - 4.0		Х	Х	Х	Х	Х	Х	Х	Х	Х			
PRIME_009_IV Access Log - 3.0		Х		Х	Х								
PRIME_011_IVIG Infusion - 2.0		Х		Х	Х								
PRIME_050_Research Lab-Blood - 3.0		Х			Х	Х	Х		Х				
PRIME_050_Research Lab-Blood - 2.0										Х			
PRIME_051_Research Lab-Plasma - 3.0		Х			Х	Х	Х		Х				
PRIME_051_Research Lab-Plasma - 2.0										Х			
PRIME_025_Transplant - 2.0										Х			
PRIME_013_Concomitant Medications - 6.0											Х		
PRIME_020_Adverses Event Log - 3											Х		
PRIME_040_Protocol Deviation Log - 3											Х		
PRIME_045_SAE-Serious Adverse Event - 6.0												Х	
PRIME_035_Final Status - 1.0													Х

Enrollment/Baseline:

PRIME_	_000_	PROBE Link - 2.0	
PRIME_	_001_	Eligibility - 1.0	
PRIME	015	Exemption Reque	st - 1.0

Investigator Name:	Investigator Signature:	Date: _	
Protocol ID: P007			Study Subject ID:

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

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 Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Enrollment/Baseline	
Event Date:	

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 O No O Unknown		
A2. Enrolled in PROBE *	○ Yes ○ No ○ Unknown	
A3. HPE for BA within the p	orevious 3 days O Yes O No O Unknown	
A4. Subject's gestational ag	ge greater than or equal to 36 weeks at enrollment? O Yes O No O Unknown	
A5. Subject's weight greate *	er than or equal to 2000g at enrollment? O Yes O No O Unknown	
A6. Informed consent obtai	ned within 3 days following HPE O Yes O No O Unknown	

Protocol ID: P007 Study Name: PRIME Site:		Study Subject ID: Interviewer Name:
Event Name: Enrollment/Baseline Event Date:	_	
Section Title: Exclusion	Criteria	
Subject is Eligible for PRIM B1. Laparoscopic HPE or "C	E if none of the following Exclusion Criteria apply. Gallbladder Kasai" (cholecysto-portostomy) surgery was performed O Yes O No O Unknown	
B2. Biliary Atresia Splenic N	Malformation Syndrome (presence of asplenia, polysplenia or double spleen O Yes O No O Unknown)
B3. History of a Hypercoag	ulable Disorder O Yes O No O Unknown	
B4. Renal Disease (defined *	as serum creatinine > 1.0 mg/dl) prior to enrollment, or presence of comp \odot Yes \odot No \odot Unknown	olex renal anomalies found on imaging
B5. Evidence of congestive *	heart failure or fluid overload O Yes O No O Unknown	
B6. Presence of significant following HPE) *	systemic hypertension for age (defined as persistent systolic blood pressure Yes No Unknown	e ≥112 mmHg measured on at least 3 occasions
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 O Yes O No O Unknown	
B9. Previous treatment with	h intravenous immunoglobulin therapy O Yes O No O Unknown	
B10. Previous treatment wi	ith corticosteroid therapy for post-operative treatment of BA ○ Yes ○ No ○ Unknown	
B11. Previous treatment wi	ith any other investigational agent O Yes O No O Unknown	
B12. History of allergic read *	ction to any human blood product infusion O Yes O No O Unknown	
	rere concurrent illnesses (such as neurological, cardiovascular, pulmonary, induct and results of the study O Yes O No O Unknown	metabolic, endocrine, and renal disorders) that
B14. Any other clinical cone *	dition that is a contraindication to the use of IVIG ○ Yes ○ No ○ Unknown	

Protocol ID: P007		S	Study Subject ID:
Study Name: PRIME		I	Interviewer Name:
Site:			
Event Name: Enrollment/Baselin	e		
Event Date:			
Section Title: Status			
C1. Subject Eligibility Stat	tus		
*	○ Eligible		
	Eligible by exemption		
	O Not eligible		

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Enrollment/Baseline	

	PRIME_U15_Exemption Request - 1.0			
Section Title: Exemption	n Request			
Subtitle: Complete A1, A2	2 and A3 of this form to request an eligibility ϵ	exemption.		
	email will be sent to exemption committee.			
		A5 and an email will be sent to the PI and Coordinator		
Instructions: Select the Ir	nclusion/Exclusion criteria below that is not n	net 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			
	O Written informed consent obtained within 3 days of HPE			
A2. Exclusion				
	Laparoscopic HPE or gall bladder Kasai (cholecysto-portost	omy) surgery was performed		
	Biliary atresia splenic malformation syndrome (presence of	asplenia- polysplenia or double spleen) detected		
	History of a hypercoagulable disorder reported			
	O Renal Disease (defined as serum creatinine > 1.0 mg/dl) p	rior to enrollment or presence of complex renal anomalies found on imaging		
	Evidence of congestive heart failure or fluid overload			
	\bigcirc Presence of significant systemic hypertension for age (defifollowing HPE)	ned as persistent systolic blood pressure ≥112 mmHg measured on at least 3 occasions		
	O Mother known to have human immunodeficiency virus infe	ction		
	O Mother is known to be serum HBsAg or hepatitis C virus ar	tibody positive		
	O Previously treated with intravenous immunoglobulin therap	у		
	O Previously treated with corticosteroid therapy for BA post-	IPE .		
	\bigcirc Previously treated with any other investigational agent			
	History of allergic reaction to any human blood product inf	·		
	O Presence of other severe concurrent illnesses (such as new	rological-cardiovascular-pulmonary-metabolic-endocrine and renal disorders) that would		
	interfere with the conduct and results of the study O Presence of any other clinical condition that is a contraindi	asking to the use of TATC		
	Presence of any other chilical condition that is a contraining	adult to the use of 1v1g		
A3. Reason for Request				
A4. Exemption Granted				
	○ Yes			
	○ No			
A4a. If No, Reason:				
A5. Date of Decision				
Day 3-5:				
Day 5 5.				
PRIME_005_Diet - 1.0 PRIME_007_PhysicalExam - PRIME_008_Laboratory Resu				
PRIME_009_IV Access Log - PRIME_011_IVIG Infusion - PRIME_050_Research Lab-B PRIME_051_Research Lab-P	2.0 Blood - 3.0			
. Na. IL_031_NescaleII Lab-F	adina 510			
Investigator Name:	Investigator Signature:	Date:		
Protocol ID: P007		Study Subject ID:		
Study Name: PRIME		Interviewer Name:		
		and none 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)			
	☐ Cow's Milk Based Formula		
	☐ Soy Formula		
	☐ Specialized Formula		
	☐ Parental Nutrition		
	□ Solid Food		
	\square 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 Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 3-5	
Event Date:	

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 Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 3-5			
Event Date:	_		
Section Title: Vital Signs	;		
B1. Systolic BP	(mmHg)		
	(IIIIIIII)	☐ Not Done	
B2. Diastolic BP			
DZ. Diastolic Di	(mmHg)	☐ Not Done	
		- Not boile	
B3. Heart Rate			
	(beats per min)	☐ Not Done	
B4. Respiratory Rate			
	(breaths per min)	☐ Not Done	

Protocol ID: P007		Study Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 3-5		
Event Date:	_	
Section Title: Physical I	xam	
a		
Skin Exam C1. Rash *	○ -	
CI. Rusii	O Present	
	Absent	
	O Not Done	
C1a. If present indicate type	☐ Eczema	
	☐ Viral Exanthems	
	\square Acute Allergic (hives; erythema multiforme	
	☐ Diaper Rash (candida)	
	☐ Other	
If Other Rash, Specify:		
C2. Urticaria *	O Present	
	Absent	
	Not Done	
	o Not Boile	
C3. Jaundice *	Present	
	O Absent	
	O Not Done	
C3a. If present, indicate location	Skin	
	☐ Sclera	
C4. Liver Exam		
*	O Performed	
	O Not Performed	
C4a. Liver Location	O Left Side	
	O Midline	
	Right Side	
	O Not Palpable	
	O Not Done	
C4b. Liver Span	(cm at mid-clavicular line) ND or NI	0
счь. шчег эрип	(cm at mid clavicular line) ND of Ni	O NOT DOTE
		O Not Palpable
C4c. Liver Edge	(cm below costal margin) ND or NP	O Not Done
		Not Palpable
		- ·····
C4d. Liver Edge	(cm below xiphoid) ND or NP	O Not Done
		O Not Palpable
C4e. Liver Texture	○ Soft	
	O Firm	
	Hard	
	Nodular and Hard	
	O Not Palpable	
C5. Spleen Exam		
*	O Performed	
	Not Performed	
	O HOLF CHOINICU	

O Not Palpable	
Left SideMidlineRight Side	
(cm below the left (right) costal margin)	☐ Not Done
O Present	
○ Absent	
O Not Done	
Edema	
O Present	
O Absent	
O Not Done	
	 ○ Left Side ○ Midline ○ Right Side (cm below the left (right) costal margin) ○ Present ○ Absent ○ Not Done Edema ○ Present ○ Absent ○ Absent

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 3-5	

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: Coagulat Instructions: If a lab is r	ion Panel eported as below lower limit o	of detection then enter as LL. If a lab is reported as above the upper limit of le 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 Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 3-5			
Event Date:			
Section Title: Basic Me	tabolic Panel		
			ction then enter as LL. If a lab is reported as above the upper limit of 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	\square Not Done
C4. Bicarbonate (CO ₍₂₎)	(mmol/l)	Date	\square Not Done
C5. Creatinine	(mg/dl)	Date	□ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007 Study Name: PRIME		Study Subject ID: Interviewer Name:
Site:		indiviewei name
Event Name: Day 3-5		
Event Date:		
Section Title: CBC with Diffe	wantial	
		tion then enter as LL. If a lab is reported as above the upper limit of ertain labs if it is reported as such.
D1. Hemoglobin (Hgb)	(g/dl) Date	
D1. Hemoglobin (rigb)	(g/til) 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	
D4. WDC	(10° / mm²) Date	□ Not Done
D4a. Neutrophils	(%)	□ Not Done
D4b. Bands	(%)	☐ Not Done
D4c. Lymphocytes	(%)	
DHC. Lymphocytes	(70)	☐ Not Done
D4d. Monocytes	(%)	□ Not Done
D4e. Eosinophils	(%)	☐ Not Done
D5. Platelets	(10 ³ / mm ³) Date	□ Not Done
	(· / · · /	□ NOT DONE

Protocol ID: P007 Study Name: PRIME		Study Subject ID: Interviewer Name:		
Site:				
Event Name: Day 3-5				
Event Date:	_			
Section Title: Serum IgG	ì			
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 3-5		Study Subject ID: Interviewer Name:		
Event Date:				
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 Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 3-5	

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			Successfully Inserted?	why?		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 Cuable to access vein Reason unknown Other reason	Rt Arm Lft Arm Rt Hand Lft Leg Lft Leg Lft Leg Rt Foot Lft Side of Neck Torso Scalp Other					□ Not Removed

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

PRIME_011_IVIG Infusion - 2.0

Section Title: IVIG Infus	sion 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 stoppe	ed Time completed or stopped	24 hour clock 0000 format
A4. Amount of IVIG in dose (1 gm/ body weight)	/kg gm	
A5. Volume of infusion preparation	mL 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		
	○ Yes	
	○ No	

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 3-5	
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-YYYYY

A4. Barcode from Whole Blood

Protocol ID: P007		Study Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 3-5		
Event Date:		
	PRIM	1E_051_Research Lab-Plasma - 3.0
Section Title: Plasma	Specimens	
A1. Was Blood collected	for plasma at this visit?	quoted. The aliquots are to be frozen and batch shipped at a later date.
*	○ 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 PRIME_008_Laboratory Re		

Investigator Name: _____ Investigator Signature: _____ Date: ____

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 14	
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			
	☐ Other Soy Formula Other Soy, Specify Type			
	□ Not Specified			
A1d. Type of Specialized Milk				
	□ 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? (Indicate Feeding Method	check all that apply)
	☐ Nasogastric
	☐ Nasoenteric
	☐ Gastrostomy
	☐ Gastrojejunostomy
	☐ Lejunostomy
	☐ Intravenous
	☐ Not Specified

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

PRIME_007_PhysicalExam - 2.0

Section Title: Athropo	metrics		
Upload source documents			
A1. Height/Length	(cm)	☐ Not Done	
A2. Weight	(kg)	☐ Not Done	
A3. Head Circumference	(cm)	☐ Not Done	

Protocol ID: P007		Study Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 14		
Event Date:		
Section Title: Vital Sign	ıs	
B1. Systolic BP	(mmHg)	
	(IIIIIIII)	☐ Not Done
B2. Diastolic BP		
DZ. Diastolic bi	(mmHg)	☐ Not Done
		= Not boild
B3. Heart Rate		
	(beats per min)	☐ Not Done
5.5 5 .		
B4. Respiratory Rate	(breaths per min)	
	(breatis per IIIII)	☐ Not Done

Protocol ID: P007			Study Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 14			
Event Date:			
	_		
Section Title: Physical E	xam		
Skin Exam			
C1. Rash *	O Present		
	O Absent		
	O Not Done		
C1a. If present indicate type	☐ Eczema		
	☐ Viral Exanthems		
	☐ Acute Allergic (hives; erythema	multiforme)	
	3 (2,7 ,7)	,	
	☐ Diaper Rash (candida)		
	Other		
If Other Rash, Specify:			
C2. Urticaria *	O Present		
	O Absent		
	O Not Done		
C3. Jaundice *	O Present		
	Absent		
	O Not Done		
	O NOT DOILE		
C3a. If present, indicate location	Skin		
. ,	□ SKIII		
	☐ Sclera		
	□ Sciera		
C4. Liver Exam			
*	O Performed		
	Not Performed		
	O Not Performed		
C4a. Liver Location	O 1 - 6 Cid-		
	C Left Side		
	O Midline		
	O Right Side		
	O Not Palpable		
	O Not Done		
C4h Liver Coon	(and at maid alouisus law line)	ND or ND	
C4b. Liver Span	(cm at mid-clavicular line)	ND or NP	O Not Done
			O Not Palpable
C4c. Liver Edge	(cm below costal margin)	ND or NP	O Not Done
			O Not Palpable
C4d. Liver Edge	(cm below xiphoid) ND	or NP	O Not Done
			O Not Palpable
C4e. Liver Texture	○ Soft		
	O Firm		
	O Hard		
	Nodular and Hard		
	O Not Palpable		
	p		
C5. Spleen Exam			
*	O Performed		
	O Not Performed		

	O 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	
	O Not Done	
C7. Extremities: Periphera	al Edema	
*	○ Present	
	○ Absent	
	O Not Done	

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 14	

PRIME_008_Laboratory Results - 4.0

Section Title: Hepatic Fu	nction Pane	el		
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:		Study Subject ID: Interviewer Name:
Event Name: Day 14 Event Date:		
Section Title: Coagulation Pa	anel	
		detection then enter as LL. If a lab is reported as above the upper limit of e 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 Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 14			
Event Date:	_		
Section Title: Basic Meta	abolic Panel		
			f detection then enter as LL. If a lab is reported as above the upper limit of e 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	\square Not Done
C5. Creatinine	(mg/dl)	Date	□ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007		Study Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 14		
Event Date:		
Section Title: CBC with Diffe	erential	
		detection then enter as LL. If a lab is reported as above the upper limit of e for certain labs if it is reported as such.
D1. Hemoglobin (Hgb)	(g/dl) Date	☐ Not Done
D2. Hematocrit (Hct)	(%) Date	\square Not Done
D3. RBC	(10 ³ / mm ³) Date	\square 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 Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 14	
Event Date:	
Section Title: Serum IgG	
Instructions: If a lab is reported as below lower limit of detection then enter as UL. A < or > sign is acceptable for c	tion then enter as LL. If a lab is reported as above the upper limit of ertain 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 14 Event Date:			Study Subject ID: Interviewer Name:
Section Title: Hepatic Fun	ction Panel		
		ow lower limit of detection then enter as LI sign is acceptable for certain labs if it is rep	. If a lab is reported as above the upper limit of orted 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. PRIME_008_Laboratory Result PRIME_009_IV Access Log - 3. PRIME_011_IVIG Infusion - 2.	s - 4.0 .0		
Investigator Name:		Investigator Signature:	Date:

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

PRIME_005_Diet - 1.0

Section Title: Diet		
A1. What type of diet is the child on? (check all that apply)		
	☐ 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	
	☐ 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? Indicate Feeding Method	(check all that apply) \Box Oral
	☐ Nasogastric
	☐ Nasoenteric
	☐ Gastrostomy
	☐ Gastrojejunostomy
	Lejunostomy
	☐ Intravenous
	☐ Not Specified

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

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 Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 30			
Event Date:	-		
Section Title: Vital Signs			
B1. Systolic BP			
DI. Systolic Di	(mmHg)	☐ Not Done	
B2. Diastolic BP	(markle)	_	
	(mmHg)	☐ Not Done	
B3. Heart Rate			
	(beats per min)	☐ Not Done	
B4. Respiratory Rate	(breaths per min)		
	(Dreaths per min)	☐ Not Done	

Protocol ID: P007			Study Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 30			
Event Date:			
	_		
Section Title: Physical E	xam		
Skin Exam			
C1. Rash *	O Present		
	O Absent		
	O Not Done		
C1a. If present indicate type	☐ Eczema		
	☐ Viral Exanthems		
	☐ Acute Allergic (hives; erythema	multiforme)	
	3 (2,7 ,7)	,	
	☐ Diaper Rash (candida)		
	Other		
If Other Rash, Specify:			
C2. Urticaria *	O Present		
	O Absent		
	O Not Done		
C3. Jaundice *	O Present		
	Absent		
	O Not Done		
	O NOT DOILE		
C3a. If present, indicate location	Skin		
. ,	□ SKIII		
	☐ Sclera		
	□ Sciera		
C4. Liver Exam			
*	O Performed		
	Not Performed		
	O Not Performed		
C4a. Liver Location	O 1 - 6 Cid-		
	C Left Side		
	O Midline		
	O Right Side		
	O Not Palpable		
	O Not Done		
C4h Liver Coon	(and at maid alouisus law line)	ND or ND	
C4b. Liver Span	(cm at mid-clavicular line)	ND or NP	O Not Done
			O Not Palpable
C4c. Liver Edge	(cm below costal margin)	ND or NP	O Not Done
			O Not Palpable
C4d. Liver Edge	(cm below xiphoid) ND	or NP	O Not Done
			O Not Palpable
C4e. Liver Texture	○ Soft		
	O Firm		
	O Hard		
	Nodular and Hard		
	O Not Palpable		
	p		
C5. Spleen Exam			
*	O Performed		
	O Not Performed		

O Not Palpable	
Left SideMidlineRight Side	
(cm below the left (right) costal margin)	☐ Not Done
O Present	
○ Absent	
O Not Done	
Edema	
O Present	
O Absent	
O Not Done	
	 ○ Left Side ○ Midline ○ Right Side (cm below the left (right) costal margin) ○ Present ○ Absent ○ Not Done Edema ○ Present ○ Absent ○ Absent

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 30	

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
47. 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		Study Subject ID: Interviewer Name:
Event Date:	_	
Section Title: Coagulation	on 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 Subject ID:
Study Name: PRIME Site:			Interviewer Name:
Event Name: Day 30			
Event Date:	_		
Section Title: Basic Meta	abolic Panel		
			it of detection then enter as LL. If a lab is reported as above the upper limit of table 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 Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 30		
Event Date:		
Section Title: CBC with Diffe	erential	
		tion then enter as LL. If a lab is reported as above the upper limit of ertain 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 Subject ID:	
Study Name: PRIME	Interviewer Name:	
Site:		
Event Name: Day 30		
Event Date:		
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		Study Subject ID: Interviewer Name:
Site:		
Event Name: Day 30		
Event Date:		
Section Title: Hepatic Functi	ion 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 Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 30	
Event Date:	

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

	Access Type		Successfully Inserted?	why?	If "Other Reason" was selected, Specify below		Date Attempted/Inserted	Time Inserted	Date Removed	Time Removed	IV Line NOT removed
O New insertion	Peripheral intravenous PICC line Central intravenous	 ○ Preexisting ○ 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 Rt Leg Lft Leg Rt Foot Rt side of Neck Torso Scalp Other					□ Not Removed

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 30	
5 . D .	

PRIME_011_IVIG Infusion - 2.0

Section Title: IVIG Infus	ion Monitoring			
Upload source documents				
A1. Was dose administered? *	○ Yes ○ No			
A1a. If No, reason	\square Adverse event			
	\square 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 stoppe	ed Time completed or stopped	24 hour clock 0000 format		
A4. Amount of IVIG in dose (1 gm/body weight)	/kg 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				
	○ Yes ○ No			
Day 60:				
PRIME_005_Diet - 1.0 PRIME_007_PhysicalExam - 2 PRIME_008_Laboratory Resu PRIME_009_IV Access Log - PRIME_011_IVIG Infusion - 2 PRIME_050_Research Lab-Bl PRIME_051_Research Lab-Pl	lts - 4.0 3.0 2.0 ood - 3.0			
Investigator Name:	Investigator Signature		Date:	

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

PRIME_005_Diet - 1.0

Section Title: Diet						
A1. What type of diet is the child on? (check all that apply)						
	☐ 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					
	☐ Other Soy Formula Other Soy, Specify Type					
	□ Not Specified					
A1d. Type of Specialized Milk						
	□ 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? (of Indicate Feeding Method	check all that apply)
	☐ Nasogastric
	☐ Nasoenteric
	☐ Gastrostomy
	☐ Gastrojejunostomy
	☐ Lejunostomy
	☐ Intravenous
	☐ Not Specified

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

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 Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 60		
Event Date:		
Section Title: Vital Sign	ıs	
B1. Systolic BP	(mmHg)	
	(IIIIIIII)	☐ Not Done
B2. Diastolic BP		
DET DIAGONIC DI	(mmHg)	□ Not Done
		_ 100,5010
B3. Heart Rate		
	(beats per min)	☐ Not Done
D4 D D .		
B4. Respiratory Rate	(breaths per min)	
	(breatis per IIIII)	☐ Not Done

Protocol ID: P007		Study Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 60		
Event Date:		
Section Title: Physical I	Exam	
a		
Skin Exam C1. Rash *	O -	
CI. Rusii	O Present	
	Absent	
	O Not Done	
C1a. If present indicate type	☐ Eczema	
	☐ Viral Exanthems	
	\square Acute Allergic (hives; erythema multiform)
	☐ Diaper Rash (candida)	
	☐ Other	
If Other Rash, Specify:		
C2. Urticaria *	O Present	
	Absent	
	O Not Done	
C3. Jaundice *	O Present	
	O Absent	
	O Not Done	
C3a. If present, indicate location	Skin	
	☐ Sclera	
C4. Liver Exam		
*	O Performed	
	Not Performed	
C4a. Liver Location	O Left Side	
	O Midline	
	Right Side	
	O Not Palpable	
	O Not Done	
CAIL Liver Coope	(and the said also deviced the s). AID and	D
C4b. Liver Span	(cm at mid-clavicular line) ND or N	O NOT DOILE
		O Not Palpable
C4c. Liver Edge	(cm below costal margin) ND or N	
CTC. Liver Luge	(cm below costal margin)	O NOL DONE
		O Not Palpable
C4d. Liver Edge	(cm below xiphoid) ND or NP	O Not Done
, and the second	, ,	Not Palpable
		○ Not raipable
C4e. Liver Texture	○ Soft	
	O Firm	
	O Hard	
	Nodular and Hard	
	Not Palpable	
	·	
C5. Spleen Exam		
*	O Performed	
	Not Performed	

	O Not Palpable	
C5a. Spleen Location	Left SideMidlineRight Side	
C5b. Spleen Size	(cm below the left (right) costal margin)	☐ Not Done
C6. Ascites		
*	O Present	
	○ Absent	
	O Not Done	
C7. Extremities: Periphe	eral Edema	
*	O Present	
	○ Absent	
	O Not Done	

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

PRIME_008_Laboratory Results - 4.0

Section Title: Hepatic Fu	nction Pane	el				
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		Study Subject ID: Interviewer Name:
Site: Event Name: Day 60		
Event Date:	_	
Section Title: Coagulati	on Panel	
		of detection then enter as LL. If a lab is reported as above the upper limit of ble 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 Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 60			
Event Date:	-		
Section Title: Basic Meta	bolic Panel		
			of detection then enter as LL. If a lab is reported as above the upper limit of able 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	\square Not Done
C4. Bicarbonate (CO ₍₂₎)	(mmol/l)	Date	\square Not Done
C5. Creatinine	(mg/dl)	Date	☐ Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007		Study Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 60		
Event Date:		
Section Title: CBC with Diffe	erential	
		tion then enter as LL. If a lab is reported as above the upper limit of ertain 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	(10³ / mm³) Date	☐ Not Done

Protocol ID: P007 Study Name: PRIME		Study Subject ID: Interviewer Name:
Site:		The viewer Name
Event Name: Day 60		
Event Date:	_	
Section Title: Serum IgG	ì	
		f detection then enter as LL. If a lab is reported as above the upper limit of le for certain labs if it is reported as such.
E1. Serum Total IgG	(mg/dl) Date	☐ Not Done

Protocol ID: P007 Study Name: PRIME		Study Subject ID: Interviewer Name:
Site:		incrementation
Event Name: Day 60		
Event Date:		
Section Title: Hepatic	Function Panel	
		detection then enter as LL. If a lab is reported as above the upper limit of e 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 Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 60	
Event Date:	

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 O No - End of Form

Which Attempt			Successfully Inserted?	why?		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 Cuable to access vein Reason unknown Other reason	Rt Arm Lft Arm Rt Hand Lft Leg Lft Leg Lft Leg Rt Foot Lft Side of Neck Torso Scalp Other					□ Not Removed

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 60	

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 stoppe	td Time completed or stopped	24 hour clock 0000 format		
A4. Amount of IVIG in dose (1 gm/body weight)	kg 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			
	\square Other			
Other specify				
A8. Were there any infusion				
	○ Yes ○ No			
	∪ INO			

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

PRIME_050_Research Lab-Blood - 3.0

Section Title: Research Labs-Whole Blood

A1. Was Whole Blood collected at this visit

O Yes O No

DD-MMM-YYYY A2. Date Collected A3. Date Shipped DD-MMM-YYYY

A4. Barcode from Whole Blood

Protocol ID: P007 Study Name: PRIME Site: Event Name: Day 60		Study Subject ID: Interviewer Name:
Event Date:		
	PRIME_051_Research Lab-Pl	asma - 3.0
Section Title: Plasma Specime	ens	
A1. Was Blood collected for plasm	own and the plasma is aliquoted. The aliquots are to be fina at this visit? $_{\text{es}}$ \bigcirc No	rozen and batch shipped at a later date.
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 PRIME_050_Research Lab-Blood - PRIME_051_Research Lab-Plasma	3.0	

Investigator Name: _____ Date: _____

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

PRIME_005_Diet - 1.0

Constitution District				
Section Title: Diet				
A1. What type of diet is the	e child on? (check all that apply)			
	☐ 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			
	☐ 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 Indicate Feeding Method	d? (check all that apply) \Box Oral
	☐ Nasogastric
	☐ Nasoenteric
	☐ Gastrostomy
	☐ Gastrojejunostomy
	☐ Lejunostomy
	☐ Intravenous
	☐ Not Specified

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

PRIME_007_PhysicalExam - 2.0

Section Title: Athropom	etrics		
Upload source documents			
A1. Height/Length	(cm)	☐ Not Done	
A2. Weight	(kg)	☐ Not Done	
A3. Head Circumference	(cm)	☐ Not Done	

Protocol ID: P007		Study Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 90		
Event Date:		
Section Title: Vital Sign	ıs	
B1. Systolic BP	(mmHg)	
	(IIIIIIII)	☐ Not Done
B2. Diastolic BP		
DZ. Diastolic bi	(mmHg)	□ Not Done
		= Not boild
B3. Heart Rate		
	(beats per min)	☐ Not Done
B4. Respiratory Rate	(laura tha a a a a a a a a	
	(breaths per min)	☐ Not Done

Protocol ID: P007			Study Subject ID:	
Study Name: PRIME			Interviewer Name:	
Site:				
Event Name: Day 90				
Event Date:				
Section Title: Physical I	xam			
Chin France				
Skin Exam C1. Rash *	OBusset			
	Present Absent			
	Not Done			
	O NOT DOTTE			
C1a. If present indicate type	☐ Eczema			
	☐ Viral Exanthems			
	\square Acute Allergic (hives; erythema multifo	orme)		
	☐ Diaper Rash (candida)			
	☐ Other			
If Other Rash, Specify:				
C2. Urticaria *	O Present			
	O Absent			
	Not Done			
	5 Not 26115			
C3. Jaundice *	O Present			
	O Absent			
	O Not Done			
C3a. If present, indicate location	Skin			
	☐ Sclera			
	_ Scient			
C4. Liver Exam				
*	O Performed			
	Not Performed			
C4a. Liver Location				
C4a. Liver Location	O Left Side			
	O Midline			
	Right Side			
	Not PalpableNot Done			
	O Not Done			
C4b. Liver Span	(cm at mid-clavicular line) ND	or NP	O Not Done	
			Not Palpable	
			,	
C4c. Liver Edge	(cm below costal margin) ND o	or NP	O Not Done	
			O Not Palpable	
C4d. Liver Edge	(cm below xiphoid) ND or NP		O Not Done	
			O Not Palpable	
C4e. Liver Texture				
C4e. Liver Texture	○ Soft			
	O Firm			
	O Hard			
	Nodular and Hard			
	O Not Palpable			
C5. Spleen Exam				
*	O Performed			
	Not Performed			

O Not Palpable	
Left SideMidlineRight Side	
(cm below the left (right) costal margin)	☐ Not Done
O Present	
○ Absent	
O Not Done	
Edema	
O Present	
O Absent	
O Not Done	
	 ○ Left Side ○ Midline ○ Right Side (cm below the left (right) costal margin) ○ Present ○ Absent ○ Not Done Edema ○ Present ○ Absent ○ Absent

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 90	

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 Subject ID:			
Study Name: PRIME		Interviewer Name:			
Site:					
Event Name: Day 90					
Event Date:					
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 Subject ID:			
Study Name: PRIME		Interviewer Name:		
Site:				
Event Name: Day 90				
Event Date:				
Section Title: Basic Me	tabolic Panel			
			of detection then enter as LL. If a lab is reported as above the upper limit of ble 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 Subject ID:
Study Name: PRIME		Interviewer Name:
Site: Event Name: Day 90		
Event Date:		
Lvent Date.	_	
Section Title: CBC with I	Differential	
		detection then enter as LL. If a lab is reported as above the upper limit of e 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	\square 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		Study Subject ID: Interviewer Name:	
Site:			
Event Name: Day 90			
Event Date:			
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:		Study Subject ID: Interviewer Name:	
Event Name: Day 90			
Event Date:			
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 Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 90	
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-YYYYY

A4. Barcode from Whole Blood

Protocol ID: P007		Study Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 90		
Event Date:		
	P	RIME_051_Research Lab-Plasma - 3.0
Section Title: Plasma Specin	nens	
A1. Was Blood collected for plas		is aliquoted. The aliquots are to be frozen and batch shipped at a later date.
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 - PRIME_050_Research Lab-Blood PRIME_051_Research Lab-Plasm	- 3.0	

Investigator Name: _____ Date: _____

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

PRIME_005_Diet - 1.0

Section Title: Diet				
Section little: Diet				
A1. What type of diet is th	e child on? (check all that apply)			
	☐ 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				
	☐ Other Soy Formula Other Soy, Specify Type			
	☐ Not Specified			
A1d. Type of Specialized Milk	□ Alimentum			
	□ Pregistimil			
	□ Neocate			
	☐ Low Lactose			
	☐ Other Specialized Formula Other Specialized, Specify Type			
	☐ Not Specified			
A1e. Type of Parental Nutrition	☐ Total			
	□ Partial			
	□ Not Specified			

A2. How is the child fed? Indicate Feeding Method	(check all that apply) \square Oral
	☐ Nasogastric
	☐ Nasoenteric
	☐ Gastrostomy
	☐ Gastrojejunostomy
	Lejunostomy
	☐ Intravenous
	☐ Not Specified

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

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 Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 180			
Event Date:			
Section Title: Vital Signs			
B1. Systolic BP			
DI. Systone Di	(mmHg)	☐ Not Done	
B2. Diastolic BP	(mmHg)	☐ Not Done	
	(9)	□ Not Done	
B3. Heart Rate			
	(beats per min)	☐ Not Done	
B4. Respiratory Rate			
DT. Respiratory Rate	(breaths per min)	☐ Not Done	

Protocol ID: P007			Study Subject ID:	
Study Name: PRIME			Interviewer Name:	
Site:				
Event Name: Day 180				
Event Date:	_			
Section Title: Physical I	Exam			
Skin Exam	_			
C1. Rash *	O Present			
	Absent			
	O Not Done			
C1a. If present indicate type	☐ Eczema			
	☐ Viral Exanthems			
	\square Acute Allergic (hives; erythema multif	forme)		
	☐ Diaper Rash (candida)			
	☐ Other			
If Other Rash, Specify:				
C2. Urticaria *	O Present			
	O Absent			
	O Not Done			
C3. Jaundice *	O Present			
	O Absent			
	O Not Done			
C3a. If present, indicate location	Skin			
	☐ Sclera			
C4. Liver Exam				
*	O Performed			
	O Not Performed			
C4a. Liver Location	O Left Side			
	O Midline			
	O Right Side			
	Not PalpableNot Done			
	O Not Done			
C4b. Liver Span	(cm at mid-clavicular line) ND	or NP	O Not Done	
			Not Palpable	
			·	
C4c. Liver Edge	(cm below costal margin) ND	or NP	O Not Done	
			O Not Palpable	
C4d. Liver Edge	(cm below xiphoid) ND or NP		O Not Done	
			O Not Palpable	
C4e. Liver Texture	○ Soft			
	○ Sort ○ Firm			
	O Hard			
	Nodular and Hard			
	Not Palpable			
C5. Spleen Exam				
•	O Performed			
	Not Performed			

	O 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 E *	Edema O Present Absent Not Done	

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 180	

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		Study Subject ID: Interviewer Name:	
Site:			
Event Name: Day 180			
Event Date:			
Section Title: Coagulation Pa	nel		
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 Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 180			
Event Date:	-		
Section Title: Basic Meta	bolic Panel		
			t of detection then enter as LL. If a lab is reported as above the upper limit of able 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 Subject ID:
Study Name: PRIME		Interviewer Name:
Site: Event Name: Day 180		
Event Date:		
Section Title: CBC with Differ	rential	
Instructions: If a lab is reporte	ed as below lower limit of detecti	on then enter as LL. If a lab is reported as above the upper limit of rtain 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	\square 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	(%)	\square Not Done
D5. Platelets	(10 ³ / mm ³) Date	□ Not Done

Protocol ID: P007		Study Subject ID: Interviewer Name:	
Study Name: PRIME Site:		merviewer name:	
Event Name: Day 180			
Event Date:			
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		Study Subject ID: Interviewer Name:	
Site:			
Event Name: Day 180			
Event Date:			
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	\square Not Done	

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 180	
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-YYYYY

A4. Barcode from Whole Blood

Protocol ID: P007		Study Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 180		
Event Date:	_	
	PRIME_051	_Research Lab-Plasma - 3.0
Section Title: Plasma Sp	ecimens	
Whole blood is collected, sp A1. Was Blood collected for *		The aliquots are to be frozen and batch shipped at a later date.
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 - : PRIME_008_Laboratory Resu		

Investigator Name: _____ Date: ____ Date: ____

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 270	
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	
	☐ Other Soy Formula Other Soy, Specify Type	
	☐ Not Specified	
A1d. Type of Specialized Milk	☐ Alimentum	
	□ 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? Indicate Feeding Method	(check all that apply) \square Oral
	☐ Nasogastric
	☐ Nasoenteric
	☐ Gastrostomy
	☐ Gastrojejunostomy
	Lejunostomy
	☐ Intravenous
	☐ Not Specified

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

PRIME_007_PhysicalExam - 2.0

Section Title: Athropo	metrics		
Upload source documents			
A1. Height/Length	(cm)	☐ Not Done	
A2. Weight	(kg)	☐ Not Done	
A3. Head Circumference	(cm)	☐ Not Done	

Protocol ID: P007			Study Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 270			
Event Date:	_		
Section Title: Vital Signs			
B1. Systolic BP	(mmHg)		
	(mining)	☐ Not Done	
B2. Diastolic BP			
DZ. Diastolic bi	(mmHg)	☐ Not Done	
		- Not bone	
B3. Heart Rate			
	(beats per min)	☐ Not Done	
B4. Respiratory Rate			
	(breaths per min)	☐ Not Done	

Protocol ID: P007			Study Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 270			
Event Date:			
	_		
Section Title: Physical I	xam		
Skin Exam			
C1. Rash *	O Present		
	Absent		
	O 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 *	O Present		
	O Absent		
	O Not Done		
C3. Jaundice *			
C3. Jaunuice "	O Present		
	Absent		
	O Not Done		
C3a. If present, indicate location	Skin		
	_ Skiii		
	☐ Sclera		
C4 Livery France			
C4. Liver Exam *	0 - 4		
	O Performed		
	O Not Performed		
C4a. Liver Location			
C-1d. Liver Location	O Left Side		
	O Midline		
	O Right Side		
	O Not Palpable		
	O Not Done		
C4b. Liver Span	(cm at mid-clavicular line)	ND or NP	
C4D. Liver Spari	(cm at mid-claviculai line)	ND OF NP	O Not Done
			O Not Palpable
C4- Liver Ede-	(and balance and a section	ND ND	
C4c. Liver Edge	(cm below costal margin)	ND or NP	O Not Done
			O Not Palpable
CALLS IN Educ	(cm below xiphoid) ND	ND	
C4d. Liver Edge	(cm below xipnoid) ND	or NP	O Not Done
			O Not Palpable
C4a Liver Testerre			
C4e. Liver Texture	○ Soft		
	O Firm		
	O Hard		
	O Nodular and Hard		
	O Not Palpable		
CE Culara E			
C5. Spleen Exam *	0 - 4		
	O Performed		
	Not Performed		

	O Not Palpable	
C5a. Spleen Location	Left SideMidlineRight Side	
C5b. Spleen Size	(cm below the left (right) costal margin)	☐ Not Done
C6. Ascites		
*	O Present	
	○ Absent	
	O Not Done	
C7. Extremities: Peripheral	Edema	
*	○ Present	
	○ Absent	
	O Not Done	

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 270	

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 Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 270		
Event Date:		
Section Title: Coagulat	ion Panel	
		of detection then enter as LL. If a lab is reported as above the upper limit of ble 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 Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 270			
Event Date:	-		
Section Title: Basic Meta	bolic Panel		
			nit of detection then enter as LL. If a lab is reported as above the upper limit of otable 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	\square Not Done
C6. BUN	(mg/dl)	Date	☐ Not Done

Protocol ID: P007		Study Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 270 Event Date:		
Lveni Date.	-	
Section Title: CBC with D	ifferential	
		detection then enter as LL. If a lab is reported as above the upper limit of efor 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	$(10^3 / \text{mm}^3)$ Date	☐ Not Done

Protocol ID: P007	Study Subject ID:	
Study Name: PRIME	Interviewer Name:	
Site:		
Event Name: Day 270		
Event Date:		
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 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 PRIME_050_Research Lab-Bloo PRIME_051_Research Lab-Plas	s - 4.0 d - 3.0		
Investigator Name:		Investigator Signature: Date	2:

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

PRIME_005_Diet - 1.0

Section Title: Diet			
A1. What type of diet is the child on? (check all that apply)			
	☐ 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		
	☐ 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? (c Indicate Feeding Method	check all that apply)
	☐ Nasogastric
	☐ Nasoenteric
	☐ Gastrostomy
	☐ Gastrojejunostomy
	☐ Lejunostomy
	☐ Intravenous
	☐ Not Specified

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

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 Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Day 360		
Event Date:	_	
Section Title: Vital Sign	s	
B1. Systolic BP	(mmHg)	
	(IIIIIIII)	☐ Not Done
B2. Diastolic BP		
DZ. Diastolic Di	(mmHg)	□ Not Done
		— Not bond
B3. Heart Rate		
	(beats per min)	☐ Not Done
B4. Respiratory Rate	7	
	(breaths per min)	☐ Not Done

Protocol ID: P007			Stu	dy Subject ID:	
Study Name: PRIME				erviewer Name:	
Site:					
Event Name: Day 360					
Event Date:	_				
Section Title: Physical E					
occuon maci i myorcan i					
Skin Exam					
C1. Rash *	O Present				
	O Absent				
	O Not Done				
C1a. If present indicate type	☐ Eczema				
	☐ Viral Exanthems				
	Acute Allergic (hives; erythema multif	orme)			
	☐ Diaper Rash (candida)				
	□ Diaper Rasii (Caridida)				
	Other				
	_ 				
If Other Rash, Specify:					
C2. Urticaria *	0 -				
CZ. Orticaria	Present Absent				
	Not Done				
	O NOT BOILE				
C3. Jaundice *	O Present				
	O Absent				
	O Not Done				
C3a. If present, indicate location	Skin				
	☐ Sclera				
C4. Liver Exam					
*	O Performed				
	O Not Performed				
C4a. Liver Location	O Left Side				
	Midline				
	O Right Side				
	O Not Palpable				
	O Not Done				
C4b. Liver Span	(cm at mid-clavicular line) ND	or NP	O Not Done		
			O Not Palpable		
			O Not ruipuble		
C4c. Liver Edge	(cm below costal margin) ND o	or NP	O Not Done		
			O Not Palpable		
C4d. Liver Edge	(cm below xiphoid) ND or NP		O Not Done		
			O Not Palpable		
C4e. Liver Texture	0				
CHE. LIVEL TEXTUTE	○ Soft				
	○ Firm ○ Hard				
	Nodular and Hard				
	Not Palpable				
	- not apasie				
C5. Spleen Exam					
*	O Performed				
	Not Performed				

	O 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 E *	Edema O Present Absent Not Done	

udy Subject ID:
erviewer 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.			
Jpload Source document file			
11. 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 Subject ID:	
Study Name: PRIME		Interviewer Name:	
Site:			
Event Name: Day 360			
Event Date:			
Section Title: Coagulati	on 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 Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Day 360			
Event Date:			
Section Title: Basic Metab	olic Panel		
			t of detection then enter as LL. If a lab is reported as above the upper limit of able 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 Subject ID:
Study Name: PRIME		Interviewer Name:
Site: Event Name: Day 360		
Event Date:		
Event bate.		
Section Title: CBC with Differ	rential	
		tion then enter as LL. If a lab is reported as above the upper limit of ertain 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 Subject ID:		
Study Name: PRIME	Interviewer Name:		
Site:			
Event Name: Day 360			
Event Date:			
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		Study Subject ID: Interviewer Name:
Site:		interviewer name
Event Name: Day 360 Event Date:		
Section Title: Hepatic F	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 Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Day 360	
Fuent Pater	

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-YYYYY

A4. Barcode from Whole Blood

Protocol ID: P007	Study Subject ID:	
Study Name: PRIME	Interviewer Name:	
Site: Event Name: Day 360		
Event Date:		
		
	PRIME_051_Research Lab-Plasma - 3.0	
Section Title: Plasma S	pecimens	
Whole blood is collected, A1. Was Blood collected i		
*	○ 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 PRIME_008_Laboratory Re PRIME_025_Transplant - 2 PRIME_050_Research Lab- PRIME_051_Research Lab-	sults - 4.0 1.0 -Blood - 2.0	

Investigator Name: _____ Date: _____

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Transplant	
Event Date:	

PRIME_005_Diet - 1.0

Section Title: Diet				
A1. What type of diet is the child on? (check all that apply)				
	☐ 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			
	☐ Other Soy Formula Other Soy, Specify Type			
	☐ Not Specified			
A1d. Type of Specialized Milk	☐ Alimentum			
	□ 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? (c Indicate Feeding Method	check all that apply)
	☐ Nasogastric
	☐ Nasoenteric
	☐ Gastrostomy
	☐ Gastrojejunostomy
	☐ Lejunostomy
	☐ Intravenous
	☐ Not Specified

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Transplant	
Event Date:	

PRIME_007_PhysicalExam - 2.0

Section Title: Athropom	etrics		
Upload source documents			
A1. Height/Length	(cm)	☐ Not Done	
A2. Weight	(kg)	☐ Not Done	
A3. Head Circumference	(cm)	☐ Not Done	

Protocol ID: P007			Study Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Transplant			
Event Date:			
Section Title: Vital Signs			
P1 Cyctolic PD			
B1. Systolic BP	(mmHg)	☐ Not Done	
	-	in Not Bone	
B2. Diastolic BP			
	(mmHg)	☐ Not Done	
B3. Heart Rate	(beats per min)		
	(beats per min)	☐ Not Done	
B4. Respiratory Rate			
	(breaths per min)	☐ Not Done	

Protocol ID: P007			Study Subject ID:	
Study Name: PRIME			Interviewer Name:	-
Site:				
Event Name: Transplant				
Event Date:	_			
Section Title: Physical E	xam			
Skin Exam				
C1. Rash *	O Present			
	O Absent			
	O Not Done			
C1a. If present indicate type	☐ Eczema			
	☐ Viral Exanthems			
	\square Acute Allergic (hives; erythema	multiforme)		
	☐ Diaper Rash (candida)			
	☐ Other			
If Other Rash, Specify:				
C2. Urticaria *	O Present			
	Absent			
	O Not Done			
C3. Jaundice *	O -			
osi saanalee	Present Absent			
	Not Done			
	O NOL DONE			
C3a. If present, indicate location	☐ Skin			
	☐ Sclera			
C4. Liver Exam				
*	O Performed			
	O Not Performed			
C4a. Liver Location	O Left Side			
	O Midline			
	O Right Side			
	O Not Palpable			
	O Not Done			
C4b. Liver Span	(cm at mid-clavicular line)	ND or NP	O Not Done	
			O Not Palpable	
04 1: 51		ND ND		
C4c. Liver Edge	(cm below costal margin)	ND or NP	O Not Done	
			O Not Palpable	
C4d. Liver Edge	(cm below xiphoid) ND	or NP		
C4a. Liver Eage	(cm below xiphoid) ND	OF INP	O Not Done	
			O Not Palpable	
C4e. Liver Texture				
CHE. LIVEL TEXTUIE	○ Soft			
	○ Firm			
	O Hard			
	Nodular and Hard			
	O Not Palpable			
C5. Spleen Exam				
*	O Performed			
	Not Performed			

	O Not Palpable	
C5a. Spleen Location	Left SideMidlineRight Side	
C5b. Spleen Size	(cm below the left (right) costal margin)	\square Not Done
C6. Ascites		
*	O Present	
	○ Absent	
	O Not Done	
C7. Extremities: Peripheral	Edema	
*	O Present	
	O Absent	
	O Not Done	

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Transplant	
Front Date:	

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.				
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 Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Transplant		
Event Date:		
Section Title: Coagulat	ion Panel	
		of detection then enter as LL. If a lab is reported as above the upper limit of ble 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 Subject ID:
Study Name: PRIME			Interviewer Name:
Site:			
Event Name: Transplant			
Event Date:			
Section Title: Basic Meta	abolic Panel		
			of detection then enter as LL. If a lab is reported as above the upper limit of le 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 Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Transplant Event Date:		
Event Date.	_	
Section Title: CBC with I	Differential	
		detection then enter as LL. If a lab is reported as above the upper limit of efor 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	\square 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 Subject ID:					
Study Name: PRIME	Interviewer Name:					
Site:						
Event Name: Transplant						
Event Date:						
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 IqG (mq/dl) Date	☐ Not Done					

Protocol ID: P007 Study Name: PRIME			Study Subject ID: Interviewer Name:	
Site:				
Event Name: Transplant Event Date:				
Section Title: Hepatic I	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) Da	ate	☐ Not Done	
A11. Total Protein	(g/dL) Da	ate	☐ Not Done	

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Transplant	
Event Date:	

PRIME_025_Transplant - 2.0

A1. Date of Transplant

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Transplant	
Event Date:	
Section Title: PELD Scores	
B1. Calculated	
B2. Exception	
	☐ Not Done
B3. Status 1 exception	
O Not Requested	
○ Requested	
B4. Growth Failure (weight or length more tha	an two standard deviations below normal)
○ Yes	·
○ No	

Event Name: Transplant	Protocol ID: P007 Study Name: PRIME			Study Subject ID: Interviewer Name:
Event Name: Transplant Event Date: 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 Missing Missing Missing Missing C5. Donor Blood Type Missing O O O O O O O O O O O O O				THE PROPERTY HUME.
Section Title: Donor Information C1. Donor Type Cadaveric Living related donor Living urrelated donor Unknown Whole Reduces Spit C2. Donor Age Years or Months Years Missing Male Female kg Missing Missing Missing Missing				
C1. Donor Type Cadaveric Living related donor Living unrelated donor Unknown Whole Reduces Split C2. Donor Age Years or Months Years Missing Male Female kg Missing M	Event Date:			
C1. Donor Type Cadaveric Living related donor Living unrelated donor Unknown Whole Reduces Split C2. Donor Age Years or Months Years Missing Male Female kg Missing M				
Cataveric, which type Cadaveric, which type Unknown Whole Reduces Split	Section Title: Donor In	formation		
Living related donor Living unrelated donor	C1. Donor Type			
C1a. If cadaveric, which type Unknown Whole Reduces Split		O Cadaveric		
C1a. If cadaveric, which type Unknown Whole Reduces Split		O Living related donor		
C2. Donor Age Years or Months Years or Months Years Missing Missing Male Female kg Missing Missing Missing Missing Missing On Missing O		O Living unrelated donor		
○ Whole ○ Reduces ○ Split Tears or Months Years or Months Years or Months Nissing Missing Male Female kg Missing Missing Missing Missing Missing Missing Missing Missing O A O B O O O O O O O O O O O O	C1a. If cadaveric, which type	O Unknown		
C2. Donor Age Years or Months Years Missing Missing Male Female kg Missing Missing Missing kg Missing Missing O O O				
C2. Donor Age Years or Months Years Nonoths C3. Donor Gender Nissing Nale Pemale kg Missing Missing Missing Missing Missing O A O B O O				
Years or Months		O Split		
Years or Months	62.5			
C3. Donor Gender Missing Male Female kg Missing Missing Missing Missing C5. Donor Blood Type Missing A B O O	C2. Donor Age	Years or Months	O v	□ •••
C3. Donor Gender Missing Male Female kg Missing Missing Missing C5. Donor Blood Type Missing A B O O		reals of Floridis		□ Missing
 Missing Male Female kg Missing Missing A B O 			O Pionuis	
 Male Female kg Missing C5. Donor Blood Type Missing A B O 	C3. Donor Gender			
		=		
kg ☐ Missing C5. Donor Blood Type ○ Missing ○ A ○ B ○ O				
C5. Donor Blood Type One Missing A B One One		○ Female		
C5. Donor Blood Type O Missing O A O B O O		kg		
MissingABO		☐ Missing		
MissingABO	C5 Donor Blood Type			
○ A○ B○ O	C3. Donor blood Type	○ Missing		
○ B ○ O				
\circ o				
		O AB		

Protocol ID: P007 Study Name: PRIME Site: Event Name: Transplant Event Date:		Study Subject ID: Interviewer Name:
Section Title: Complic	ations	
D1. Complications prese	nt 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	
	\square Hepatorenal syndrome	
	\square No information available	
	☐ Other	
If other, specify		

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Transplant	
Fuent Date:	

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-YYYYY

A4. Barcode from Whole Blood

Protocol ID: P007		Study Subject ID:
Study Name: PRIME		Interviewer Name:
Site:		
Event Name: Transplant		
Event Date:		
		PRIME_051_Research Lab-Plasma - 2.0
Section Title: Plasma Specime	ens	
A1. Was Blood collected for plasm		na is aliquoted. The aliquots are to be frozen and batch shipped at a later date.
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 Medicati PRIME_020_Adverses Event Log - PRIME_040_Protocol Deviation Log	3	

Investigator Name: _____ Investigator Signature: _____ Date: ____

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

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	
O Acetaminophen				O mg	Once				
O Actigall			Unknown	○ G	○ QD				Ongoing
O Amoxicillin				O gtt	O BID				
O Augmentin				O ml	O TID				
O Antihistamines				○ mEq	O QID				
○ AquaDEK				Осс	O PRN				
O Bactrim				O drops	○ EOD				
O Benedryl				O puffs	○ Qw				
O Branch chain amino acids				O tabs	O 1/month				
○ Calcium				O IU	○ 3/week				
Clotrimazole anti-fungal cream				0	○ q 4 hr				
O Cholestyramine (e.g. Questran)				Application	O q 6 hr				
O Desitin diaper rash cream				O Unknown	O q 12 hr				
O Diphenhydramine					0				
O Duocal					Unknown				
O Furosemide (e.g. Lasix)									
O Hydrocortisone 1% cream									
Medium chain triglycerids (MCT) oil									
O Mephyton									
Methylprednisolone									
O Multivitamin									
O Neomycin									
Nystatin									
O Polycose									
O Prednisolone									
O Prednisone									
Rifampin									
O 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)									
D5W(Dextrose 5% in water) D5NS									
O D5 1/2NS									
○ NaCl 0.9% ○ KCl									
Ranitidine									
Cefotaxime									
O Ciprofloxacin									
O Fluconazole									
Oxycodone									
O Vaccine H Influenza B									
O Vaccine pneumoccocal									

Page 138 of 146

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

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: AE/Med/Deviation Logs	

PRIME 020 Adverses Event Log - 3

				!	PRIME_U2	.U_Auveise	es Event Lo	·g - 3				
Section Title: Ad	verse E	vents										
Subtitle: If an Ever Please use the Cor							the ChiLDRE	N Website wh	en Specifyir	ng the event a	and Severity	grading.
Instructions:												
Adverse Evenet column.		ose an	event fron	n the drop	down list. Er	nter one even	it per line. If t	he event is no	ot in the list,	, choose Othe	er, and Spec	ify in the
2. Onset Date 3. Resolution AE is ongoine 4. Severity: In 5. Expected of 6. Relationshic Clinician/Invo 7. Did AE occuments directly after 8. Action Take dose change 9. Outcome: In 10. Treatment Medication Lossect one response.	Date: Eig, leave to dicate the r Unexpp to IVI estigator. ur during infusion. een regar or discoondicate to Require og.)	nter the chis field see sever ected in the control of the chis in	e date the Add blank.) Writy grade of Indicate if P-SMZ, Uin infusion? Study Drug d, on Form come of the cicate if med	Adverse Evaluation Adverse Evaluation AE has fit the AE. It this is an exo: For each at the AE of the AE o	vent ended. as ended, up For accurate expected ad ach study me occurred duri e the action to omitant Media	If complete d date this field grading, refeverse event, a dication, indi- ing the IVIG i aken with IVI cations.)	late is unknow I with the AE e r to "Common as outlined in cate if it had a nfusion perioc G in response	on, enter an e end date. In Terminology the protocol. In causal effect In the AE. (R	stimate. Par Criteria for t on that Ad d during IV deport action	Adverse Event, a insertion, durn taken for Ur	not accepted as reported ring infusion so and TMP	by the n, or P-SMZ,
Were any Adverse Everyerienced? *	vents	O Ye										
			Resolution Date		Expected or Unexpected	Relationship to IVIG	Relationship to TMP-SMZ	Relationship to Urso		Action taken regarding IVIG	Outcome:	Treatment required
Other Acholic Stools Allergic reaction Allergic rhinitis Anemia Ascites				Grade 1 Mild Grade 2 Moderate Grade 3 Severe	C 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	Recovered Recovered with sequelae Ongoing	○ Yes ○ No ○ Unknown

Auverse Event:	if Other		Date	Severity:	Unexpected	to IVIG		to Urso		regarding	outcome:	required
Other Acholic Stools Allergic reaction Allergic rhinitis Anemia Ascites Biliary tract infection Bronchial infection IV Catheter- related infection Congestion Constipation Cough Creatinine increased Decreased Feeding Dehydration Diarrhea Diaper Rash Difficulty breathing Eczema Edema Elevated Bilirubin Elevated Elevated				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
Transaminases	l	1	1	1		1	1	1			l	l

Elevation In AST							
& ALT							
Elevation in							
systolic blood pressure >112mmHG							
O Emesis							
O Epistaxis							
O Failure to Thrive							
○ Feeding							
Intolerance							
O Fever							
O Flu-like symptoms							
Fussiness Gastrointestinal							
disorder							
O Headache							
O Hypertension							
O Hypoalbuminemia							
O Hypocalcemia							
O Hypotension							
O Hypothroidism							
O Inadequate							
Weight Gain Increased PT/INR							
Increased PI/INR Increased							
Sleepiness							
O Influenza A							
O Infusion site							
extravasation							
Irritability Infusion related							
reaction							
O Jaundice							
O Jaundice – sceral							
O Jaundice – skin							
O Leukocytosis							
O Localized edema							
O Edema-limbs							
O Low Iron							
O Neutropenia							
O Nasal congestion							
Oral Thrush							
Otitis externa							
Otitis media Poor Nutritional							
Status							
O Poor Weight Gain							
O Pruritis							
O Rash							
O Reflux							
O Roseola							
○ RSV							
O Sinus Infection							
O Skin infection							
O Sore Throat							
Strep PharyngitisTinea Capitis-							
Clinea Capitis- Ringworm							
O Upper Respiratory							
Infection							
O Urinary tract infection							
Urticaria							
O Viral Illness							
O Vomiting							
Weight Loss							
O Wheezing							
Protocol ID: P007				C: 1	Subject ID:		

Protocol ID: P007 Study Subject ID:_____

Study Name: PRIME				Interviewer Nar	ne:	
Site:						
Event Name: AE/Med	d/Deviation Logs					
Event Date:						
		DDTME 040 F		•		
		PRIME_U4U_F	Protocol Deviation Log	- 3		
Section Title: I	Protocol Deviation					
Instructions:						
Select Only Or	ne response for each field.					
Mara thara any	deviations for this subject?					
*	○ yes ○ no					
	○ yes ○ no					
Which Visit?	Deviation	If Other deviation, specify	If Study Procedure, which one	Reason	Additional Comments	
O Not visit related	O Missed visit		O Vitals	○ Site error		
O Enrollment	O Informed Consent deviation		O Anthropometrics	O Subject refused		
O Day 3-5	O Study procedure not completed		O Physical Exam	O Subject too ill		
O Day 14	O IVIG not given		O Con meds assessment	O Time constraints		
O Day 30	O IVIG dose error		O Diet assessment	Other		
O Day 60	○ TMP-SMZ dose error		O Clinical Lab	O Unknown		
O Day 90	\bigcirc ursodiol dose error		O Research Lab			
O Day 180	Out of Window		Other			
O Day 270	Other					
O Day 360						
O Transplant						
SAE:						
PRIME_045_SAE-	Serious Adverse Event - 6.0					
Investigator Nam	e:	Investigator Signature: _	Dat	te:		

Study Subject ID:
Interviewer Name:

PRIME_045_SAE-Serious Adverse Event - 6.0

Section Title: Serious Adverse Event					
Instructions: This form will	Instructions: This form will be completed for all SAEs regardless of expectedness or relatedness				
A0. Has the subject had a li	ver transplant?				
*	○ Yes				
	○ No				
A0a. Date of Transplant	(DD-MMM-YYYY)				
A1. AE Diagnosis *					
A2. AE Description					
A2a. Subject's weight at time of SA	NE? (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					
*	O Recovered/resolved				
	○ Recovering/resolving				
	O Not recovered/not resolved				
	O Recovered/resolved w. sequelae				
	○ Fatal ○ Unknown				
	Unknown				
A5a. End Date	(DD-MMM-YYYY) TIME: (0000 24 hour clock)				
A6. Indicate Severity of SAE	E (Refer to CTCAE criteria for definitions).				
	○ Grade 1 Mild				
	○ Grade 2 Moderate				
	O Grade 3 Severe				
	Grade 4 Life-threatening or disabling AE				
	○ Grade 5 Death related to AE				
A7. Causality of SAE (relation	onship to Study medications)				
*	O Definite*				
	O Probable*				
	O Possible*				
	○ Unlikely ○ Not assessable				
	Not assessable				
*A7a. If causality is Definite	e, 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?		
at a second seco	○ Yes	
	O No	
A9a. If Yes, please check all that app	oly 🗆 Fatal	
	Congenital Abnormality	
	☐ Hospitalization intial or prolonged	
	Hospitalization initial or prolonged	
	Required intervention to prevent permanent impairment/damage	
	☐ Life-threatening	
	☐ Significant Disability	
	_ organicant bloading	
	Other If Other, Specify:	
A10. Date of last IVIG Dose	(DD MMM VAAAA)	
	(DD-MMM-YYYY)	
A11. Action Taken with IVIG	due to this event	
	□ None	
	☐ Infusion rate decreased	
	☐ Infusion interrupted	
	Three Discountings of	
	☐ IVIG Discontinued	
A11a. Did AE abate after IVI	G stopped or rate reduced?	
	○ Yes	
	○ No	
	O Not Applicable	
A42 U.L. 16 1645		
A12. Upload final SAE summary here		
A13. Upload Source document		
- !		
Final Status:		
Investigator Name:	Investigator Signature:	Date:

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

PRIME_035_Final Status - 1.0

Section Title: Final Stat	us		
AO. 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		
	O Death		
	Subject transferred		
	Other		
Other Reason: Specify			
A1a. Reason PI withdrew	Cubiact		
Ala. Reason FI Withurew	☐ Medical concern		
	□ Medical concern		
	☐ Not compliant		
	☐ Other Other Reason: Specify		
A1b. Reason Subject volu	•		
	☐ Study procedures were not acceptable		
	☐ Unable to adhere to visit schedule		
	☐ Adverse event		
	☐ Lack of Efficacy		
	☐ Other Other Reason: Specify		
A1c. Which study procedu	ire was not acceptable?		
Azer Willer Study procede	Other Reason: Specify Other Reason: Specify		
	O Blood draws		
	Other		
A1d. Transferred to Site#	:		
A1e. New Subject ID#:			
Unscheduled:			
Unscheduled:			
PRIME_050_Research Lab-E PRIME_051_Research Lab-F			
Townsties to Al	T	Data	
	Investigator Signature:		
Protocol ID: P007		Study Subject ID:	

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

 \bigcirc Yes \bigcirc No

A2. Date Collected DD-MMM-YYYY

A3. Date Shipped DD-MMM-YYYY

A4. Barcode from Whole Blood

Protocol ID: P007	Study Subject ID:
Study Name: PRIME	Interviewer Name:
Site:	
Event Name: Unscheduled	
Frenk Date:	

PRIME_051_Research Lab-Plasma - 3.0

	•		
Section Title: Plasma Specimens			
	I, spun down and the plasma is alique I for plasma at this visit?	oted. The aliquots are to be frozen and batch shipped at a later date.	
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			