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FORM 1B: DOCUMENTATION OF ELIGIBILITY

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
AE1ID	AE1ACROS	AE1STFID	AE1RANDN

Randomization Date: AE1RDATE / AE1RDATE / AE1RDATE
Month Day Year

Time: AE1RDH : AE1RDM
24 hour clock

1B.1. Center Name:

 AE1CNAM

1B.2. Randomization number:

 AE1RANDN2

1B.3. Date and time of birth:

 AE1BDAT / AE1BDAT / AE1BDAT
Month Day Year
 AE1BH : AE1BM
24 hour clock

1B.4. Has a sibling(s) been enrolled in this study ?

Yes No AE1SEN
1 0

1B.4.a. Enter Randomization #(s):

 AE1SE1 : AE1SE1 / AE1SE2 : AE1SE2

1B.5. INCLUSION CRITERIA REVIEW:

1B.5.a. Gestational Age: weeks: AE1GAW

days: AE1GAD

1B.5.a.i. How was GA determined? (select one) AE1GAHD

0 US < 20 wks 1 Dates 2 Physical Exam

1B.5.a.ii. Is gestational age ≤ 28 weeks?

1 Yes 0 No

1B.5.b. Age in days: AE1IAGED

(DOB = Day 1)

1B.5.b.i. Is infant between 7-14 days of life?

1 Yes 0 No

1B.5.c. Intubated and mechanically ventilated between 7 - 14 days of life?

1 Yes 0 No

1B.5.d. Plan to treat with Inhaled Nitric Oxide if enrolled in TOLSURF?

1 Yes 0 No AE1PLTRINO

1B.5.e. Are any of the 4 Inclusion Criteria listed above answered "No"?

1 Yes 0 No
1 0

Complete Form 19 - Protocol Violations, Q19.2.a.

AE1IPRVIO

Continue to page 2 and answer all questions.

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FORM 1B: DOCUMENTATION OF ELIGIBILITY

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
AE2ID	AE2ACROS	AE2STFID	AE2RANDN

1B.6. EXCLUSION CRITERIA REVIEW:	
1B.6.a. Infant has serious congenital malformations or chromosomal abnormalities? (see MOP) AE2SCMCA	<input checked="" type="radio"/> Yes <input type="radio"/> No
1B.6.b. Is life expectancy < 7 days starting at DOL 7? AE2LEL	<input checked="" type="radio"/> Yes <input type="radio"/> No
1B.6.c. Infant is clinically unstable. (see MOP) AE2CLINUNS	<input checked="" type="radio"/> Yes <input type="radio"/> No
1B.6.d. QUESTION REMOVED, 11/7/12 AE2IVH	
1B.6.e. Treated with surfactant within the 48 hours prior to enrollment. AE2TSUR	<input checked="" type="radio"/> Yes <input type="radio"/> No
1B.6.f. Unlikely to be able to collect primary endpoint data at 36 weeks. AE2EPTDATA	<input checked="" type="radio"/> Yes <input type="radio"/> No

1B.6.g. Are any of the 6 Exclusion Criteria listed above answered "Yes"?

Yes No → **Complete Form 19 - Protocol Violations, Q19.2.b.** **AE2EPRVIO**

1B.7. CONSENT and HIPAA FORMS REVIEW:	
1B.7.a. Have Consent and HIPAA forms been signed and dated? AE2CONHIP	<input checked="" type="radio"/> Yes <input type="radio"/> No
<div style="border: 1px solid black; padding: 5px; display: inline-block;"> 1B.7.b. Date signed: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small> </div> AE2CONSIGD	
<div style="border: 1px solid black; padding: 5px; display: inline-block;"> Complete Form 19 - Protocol Violations, Q19.2.c. </div>	
Review signed ICF before answering questions below:	
1B.7.c. Was parental permission obtained for banking samples? AE2BNKSMP	<input checked="" type="radio"/> Yes <input type="radio"/> No
1B.7.d. Was parental permission obtained for DNA harvesting? AE2DNAHRVG	<input checked="" type="radio"/> Yes <input type="radio"/> No

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FORM 2: PERINATAL DEMOGRAPHICS DATA

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
APDID	APDACROS	APDSTFID	APDRANDN

2.1. **MOTHER'S AGE:** **APDMAGE**

2.2. **ETHNIC ORIGIN OF MOTHER:** (self identified - select one) **APDETH**

1 Hispanic or Latino 0 NOT Hispanic or Latino 8 Unavailable/Unknown

2.3. **RACIAL ORIGIN OF MOTHER:** (self identified - select all that apply)

1 White **APDRACWH** 1 American Indian/Alaska Native **APDRACAI**
APDRACBL 1 Black or African American 1 Native Hawaiian or other Pacific Islander
 1 Asian **APDRACAS** 1 Unavailable/Unknown **APDRACNH**
APDRACNA

2.4. **MATERNAL EDUCATION:** (select one) **APDEDU**

0 Some education, high school not complete 1.5 Some college
 1 High school graduate 3 Graduate study
 2 College graduate 8 Unknown/Unavailable

2.5. **MATERNAL MEDICAL HISTORY:** (current)

2.5.a. Diabetes (Any) 1 Yes 0 No 8 Unknown **APDDIA**

2.5.b. Hypertension (Any) 1 Yes 0 No 8 Unknown **APDHYP**

2.5.c. Asthma 1 Yes 0 No 8 Unknown **APDAST**

2.5.d. PPRM 1 Yes 0 No 8 Unknown **APDPPR**

2.6. **PREGNANCY HISTORY:**

2.6.a. Gravida (Total number of pregnancies, including current): **APDGRAV**

2.6.b. Para (Total number of live births - number should include this birth): **APDPARA**

2.6.c. Multiple gestation this birth: 2 Twin 3 Triplet 4 Quad 0 No 8 Unknown

APDMGW 2.6.c.i. Is this infant a member of a monozygous twin? 1 Yes 0 No 8 Unknown

APDIUD 2.6.c.ii. Was there an intrauterine demise? 1 Yes 0 No 8 Unknown

2.6.d. Pre-Natal Care: 1 Yes 0 No 8 Unknown **APDPREC**

2.7. **MATERNAL CORTICOSTEROID ADMINISTRATION:** **APDCORT**

2.7.a. Did mother receive antenatal corticosteroids? 1 Yes 0 No 8 Unknown

APDCORTFU 2.7.a.i. Was this a full course of corticosteroids? 1 Yes 0 No 8 Unknown
(see MOP for definition)

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FORM 3: INFANT DELIVERY DATA

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
: AIDID	AIDACROS	AIDSTFID	AIDRANDN

3.1. **GENDER:** Female Male **AIDGEND**

3.2. **BIRTH WEIGHT:** [][][][] gms **AIDWTG**

3.3. **PHYSICAL MEASUREMENTS AT BIRTH:**
Head Circumference (to the nearest 0.5cm): [][] . [] cm Unknown **AIDHCU**

3.4. **DELIVERY ROUTE:** Vaginal Caesarean Unknown **AIDBERT**

3.5. **APGAR SCORES:** 3.5.a. One Minute [][] Not recorded **AIDAP1N**

3.5.b. Five Minute [][] Not recorded **AIDAP5N**

3.5.c. Ten Minute [][] Not recorded **AIDAP10N**

3.6. **DELIVERY RESUSCITATION REQUIRED:** Yes No Unknown **AIDDR**

3.6.a. Type of resuscitation (select all that apply)

- Oxygen **AIDDOXY** Intubation/Ventilation **AIDINTVE** NCPAP **AIDNCPAP**
- Bag and Mask Ventilation **AIDBAGMA** Chest Compressions **AIDCHEST** Epinephrine **AIDEPIN**

3.7. **SURFACTANT THERAPY PRIOR TO ENROLLMENT:** Yes No Unknown **AIDSURF**

3.7.a. List all surfactant therapy doses:		FOR ALL BELOW			
Date of Dose (mm/dd/yy)	Time (24 hour clock)	1 Survanta	2 Infasurf	3 Curosurf	4 Other
1. [][] / [][] / [][] AIDSTDT1	[][] : [][] AIDSTTH1 [][] AIDSTTM1	<input type="radio"/> AIDSTB1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. [][] / [][] / [][] AIDSTDT2	[][] : [][] AIDSTTH2 [][] AIDSTTM2	<input type="radio"/> AIDSTB2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. [][] / [][] / [][] AIDSTDT3	[][] : [][] AIDSTTH3 [][] AIDSTTM3	<input type="radio"/> AIDSTB3	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. [][] / [][] / [][] AIDSTDT4	[][] : [][] AIDSTTH4 [][] AIDSTTM4	<input type="radio"/> AIDSTB4	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>





FORM 4: PRE-ENROLLMENT CO-MORBIDITIES OF PREMATURITY

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMRID	CMRSTFID CMRACROS		CMRRANDN

4.1. NEUROLOGIC: Pre-Enrollment

CMRIVH

4.1.a. IVH: Yes No Unknown

4.1.a.i. IVH Grade: Grade 1 or 2 Unilateral Grade 3 - 4 **CMRIVHGRD**

4.1.a.ii. How was IVH determined? MRI HUS CT Scan Unknown **CMRIVHCTS CMRIVHUNK**
(select all that apply) **CMRIVHMRI CMRIVHHUS** (No MRI / HUS/ CT scan done)

4.1.b. Cystic PVL: Yes No Unknown

CMRPVL

4.1.b.i. How was PVL determined? MRI HUS CT Scan Unknown **CMRPVLCTS CMRPVLUNK**
(select all that apply) **CMRPVLMRI CMRPVLHUS** (No MRI / HUS/ CT scan done)

4.2. GASTROINTESTINAL: Pre-Enrollment

4.2.a. NEC:

NEC is defined as: pneumotosis, hepato-biliary gas, or pneumoperitoneum AND with one or more of the following: bilious gastric aspirate or emesis, abdominal distension, or occult or gross blood in stool not from fissure.

CMRNEC Yes No Unknown
 1 0 8

4.2.a.i. Date of diagnosis: **CMRNECD** / /
Month Day Year

4.2.a.ii. Outcome: NEC with surgery NEC without surgery **CMRNECTYPE**
(inc. peritoneal drain placement)

4.2.a.iii. Date of surgery: **CMRNECSURD** / /
Month Day Year

4.2.b. Isolated GI Perforation without NEC:

CMRGIP Yes (laparotomy or drain without laparotomy) No Unknown
 1 0 8

4.2.b.i. Date of diagnosis: **CMRGIPD** / /
Month Day Year

4.3. PULMONARY: Pre-Enrollment

4.3.a. Severe Pulmonary Interstitial Emphysema (PIE): (see MOP for definition)

CMRPIE Yes No Unknown
 1 0 8

4.3.a.i. Date of diagnosis: **CMRPIED** / /
Month Day Year

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FORM 4: PRE-ENROLLMENT CO-MORBIDITIES OF PREMATURITY

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMSID	CMSACROS	CMSSTFID	CMSRANDN

4.3.b. Severe Pulmonary Hemorrhage: Yes No Unknown
(see MOP for definition)

CMSPUL

4.3.b.i. Date of diagnosis:

<input type="text"/>	<input type="text"/>	<input type="text"/>
Month	Day	Year

CMSPUID

4.3.c. Pneumothorax (requiring a chest tube): Yes No Unknown

CMSPNE

4.3.c.i. Date of chest tube:

<input type="text"/>	<input type="text"/>	<input type="text"/>
Month	Day	Year

CMSPNED

4.4. CARDIOVASCULAR: Pre-Enrollment

4.4.a. Was infant treated with prophylactic Indomethacin/Ibuprofen?

Yes No Unknown

CMSINDIBU

4.4.b. PDA requiring treatment: (see MOP)

Yes No Unknown

CMSPDAT

4.4.b.i. PDA treated with therapeutic Indomethacin/Ibuprofen?

Yes No Unknown **CMSPINDIBU**

4.4.b.ii. Ligation **CMSPLIG**

Yes No Unknown

4.4.b.iii. Date of surgery:

<input type="text"/>	<input type="text"/>	<input type="text"/>
Month	Day	Year

CMSPLIGD

4.4.c. Hypotension:

(see MOP for definition) Yes No Unknown

CMSHYP

4.4.c.i. Treated w Dopamine > 20 mcg/kg/min > 24 hours	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	CMSDOP
4.4.c.ii. Treated w 2 or more pressor agents > 24 hours (includes hydrocortisone)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	CMSPRESS



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FORM 4: PRE-ENROLLMENT CO-MORBIDITIES OF PREMATURITY

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMTID	CMTACROS	CMTSTFID	CMTRANDN

4.4. CARDIOVASCULAR: Pre-Enrollment (cont.) **CMTPHY**

4.4.d. Pulmonary Hypertension: Yes No Unknown
(see MOP)

4.4.d.i. How was diagnosis determined: (select all that apply)
 Clinical Echocardiogram Unknown
CMTPHYCLI **CMTPHYECH** **CMTPHYUNK**

4.4.d.ii. Date of diagnosis: / /
 Month Day Year
CMTPHYD

4.5. CULTURE PROVEN SEPSIS: Pre-Enrollment

Record for blood, CSF, urine, or TA culture samples. Record the dates of each positive sample drawn for each episode of sepsis/infection that resulted in treatment with antibiotics, antifungals or antivirals for ≥ 7 days.

4.5.a. Did infant have culture proven sepsis? Yes No Unknown
CMTSEP

4.5.a.i. Date specimen drawn: / /
 Month Day Year
CMTSD1

Specimen type: (select one) blood CSF Urine TA
 Organism: (select all that apply) Bacterial Fungal Viral
CMTSPE1 **CMTBAC1** **CMTFUN1** **CMTVIR1**

4.5.a.ii. Date specimen drawn: / /
 Month Day Year
CMTSD2

Specimen type: (select one) blood CSF Urine TA
 Organism: (select all that apply) Bacterial Fungal Viral
CMTSPE2 **CMTBAC2** **CMTFUN2** **CMTVIR2**

4.5.a.iii. Date specimen drawn: / /
 Month Day Year
CMTSD3

Specimen type: (select one) blood CSF Urine TA
 Organism: (select all that apply) Bacterial Fungal Viral
CMTSPE3 **CMTBAC3** **CMTFUN3** **CMTVIR3**

4.5.b. Did infant have RSV pneumonia? Yes No Unknown
CMTRSV

4.5.b.i. Date first positive TA culture or DFA collected: / /
 Month Day Year
CMTRSVD



FORM 5: PRE-ENROLLMENT RESPIRATORY PARAMETERS

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Page #	Randomization #
PR1ID	PR1ACROS	PR1STFID	PRAPAGEN Page of 5	PR1RANDN

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Date of Birth (mm/dd/yy): (fake field)

Complete these pages from birth up to day of enrollment.

Hour	DOL	Date (mm/dd/yy)	Time (24 hr)	PEEP/CPAP	MAP	Fi O ₂	NC Flow LPM	iNO ppm	Respiratory Status (code) *
PRADOLHR	D:								
	D:								
	D:	PRARDATE							
	D:		PRATIMEH						
	D:		PRATIMEM						
	D:			PRAPEEP					
	D:			PRAMAP					
	D:					PRAFIO2			PRARCODE
	D:						PRANCF	PRAINO	

EACH LINE REPRESENTS ONE RECORD WHICH WILL INCLUDE BANNER INFO. (DATE AND TIME OF BIRTH ARE FAKE FIELDS)

PRADOLHR is a combo of the first 2 columns, and the data will look like this: 0801. The master table has added fields that are a subset of this field and they are PRAHR and PRADOL.

- * Respiratory Support Status:
- 1=CMV
 - 2=HFV
 - 3=NIMV (Nasal IMV, SiPAP, BiPAP)
 - 4=CPAP
 - 5= HFNC or NC > 2 lpm
 - 6=O2:NC (≤ 2 lpm or Oxyhood)
 - 7=Ext in RA, off all support



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FORM 6: INHALED NITRIC OXIDE DELIVERY

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TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
INOID	INOACROS	INOSTFID	INORANDN

Box 1: Inhaled Nitric Oxide start and dosing schedule per NO CLD Protocol.

(see MOP)

- 1 - Initiate iNO at 20 PPM
- 2 - Wean to 10 PPM at 4 days ± 24 hours after iNO started
- 3 - Wean to 5 PPM at 11 days ± 24 hours after iNO started
- 4 - Wean to 2 PPM at 18 days ± 24 hours after iNO started
- 5 - Discontinue at 25 days ± 24 hours after iNO started

NOTE: USE OF iNO PRIOR TO DOL 7 IS NOT PART OF THE TOLSURF STUDY

6.1. Report date/time iNO treatment began and concentration at iNO start.

1. INOINOSTD1 / INOINOSTH1 INOINOINC1
 Month Day Year Time: (24h-clock) Concentration: PPM

6.1.a. Report subsequent iNO dose changes below:

2. INODOCHGD2 INODOCHGH2 INODOCHGM2 INODOCHGC2
 Month Day Year Time: (24h-clock) Concentration: PPM

3. INODOCHGD3 INODOCHGH3 INODOCHGM3 INODOCHGC3
 Month Day Year Time: (24h-clock) Concentration: PPM

4. INODOCHGD4 INODOCHGH4 INODOCHGM4 INODOCHGC4
 Month Day Year Time: (24h-clock) Concentration: PPM

5. INODOCHGD5 INODOCHGH5 INODOCHGM5 INODOCHGC5
 Month Day Year Time: (24h-clock) Concentration: PPM

6.1.b. Did any iNO dose in Q6.1.a. deviate from the iNO NO CLD dosing schedule in Box 1, at the top of this form? Yes No
 INOINODVIA Document on Form 18: Protocol Deviations, Q18.2.b.

6.2. Received additional iNO after completing iNO course per NO CLD Protocol?

INOADDINO Yes No Unknown

6.2.a. Report these iNO doses below:

6. INODOCHGD6 INODOCHGH6 INODOCHGM6 INODOCHGC6
 Month Day Year Time: (24h-clock) Concentration: PPM

7. INODOCHGD7 INODOCHGH7 INODOCHGM7 INODOCHGC7
 Month Day Year Time: (24h-clock) Concentration: PPM

8. INODOCHGD8 INODOCHGH8 INODOCHGM8 INODOCHGC8
 Month Day Year Time: (24h-clock) Concentration: PPM

9. INODOCHGD9 INODOCHGH9 INODOCHGM9 INODOCHGC9
 Month Day Year Time: (24h-clock) Concentration: PPM

6.2.b. Did any iNO dose in Q6.2.a. deviate from the iNO dosing schedule in Box 1, at the top of this form? Yes No
 INOINDVIA2 Document on Form 18: Protocol Deviations, Q18.2.c.

6.3. Date iNO discontinued:

INOINODISC
 Month / Day / Year

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FORM 7A: INITIAL STUDY DRUG DELIVERY

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
DRAID	DRAACROS	DRASTFID	DRAANDN

7A.1. STUDY DRUG DOSE/SHAM: 1 ● #1 7A.1.a. Was dose #1 administered? Yes 1 No 0 **DRADOS1ADM**

7A.1.b. Age in days: (If not dosed between DOL 7-14, complete a Form 18, Protocol Deviation, Q18.2.e) **Complete Form 19: Protocol Violations, Q19.2.e.**

7A.1.c. Was Tracheal Aspirate obtained prior to study drug dose/sham? Yes 1 No 0 **DRATAO** / / **DRATADH** : : **DRATADM**

7A.1.d. Problem with Tracheal Aspirate sampling? (see MOP) Yes 1 No 0 **DRATAPROB** **Enter on Form 13A: Adverse Events, Q13A.20.**

7A.1.e. Is infant currently receiving Inhaled Nitric Oxide? Yes 1 No 0 **DRAINOADM**

7A.1.e.i. iNO concentration at study drug dose/sham #1: PPM **DRAINOCN** **Complete Form 19: Protocol Violations, Q19.2.h.**

7A.2. STUDY DRUG/SHAM - DATE & TIME DOSE #1 GIVEN: Note: If possible, please avoid suctioning for at least 4 hours after after study drug/sham dosing procedure. **DRASURD** / / **DRASURDH** : : **DRASURDM**

Time	Vent Mode CMV or HFV	PIP/ΔP	PEEP	MAP	Fi O ₂	O ₂ Sat
0 (pre)	<input checked="" type="radio"/> 1 <input type="radio"/> 0 DRAVM0	<input type="text"/> DRAPI0	<input type="text"/> DRAPEEP0	<input type="text"/> DRAMAP0	<input type="text"/> DRAFI0	<input type="text"/> DRAO2S0
1hr post	<input checked="" type="radio"/> 1 <input type="radio"/> 0 DRAVM1	<input type="text"/> DRAPI1	<input type="text"/> DRAPEEP1	<input type="text"/> DRAMAP1	<input type="text"/> DRAFI1	<input type="text"/> DRAO2S1
2hr post	<input checked="" type="radio"/> 1 <input type="radio"/> 0 DRAVM2	<input type="text"/> DRAPI2	<input type="text"/> DRAPEEP2	<input type="text"/> DRAMAP2	<input type="text"/> DRAFI2	<input type="text"/> DRAO2S2

7A.2.a. Study drug dose/sham #1 tolerance WITHIN <=4 HOURS AFTER DOSING PROCEDURE:

7A.2.a.i. **DRARESP** 1 0 Yes No Severe respiratory decompensation (defined as increased RSS > 5 above baseline sustained > 24 hr) - *If Yes, enter on Form 13A: AE, Q13A.3. and complete Form 21: SAE, Q21.2.*

7A.2.a.ii. **DRACPRGVN** 1 0 Yes No Severe cardiopulmonary decompensation requiring CPR with chest compressions and cardiac meds - *If Yes, enter on Form 13A: AE, Q13A.4. and complete Form 21: SAE, Q21.3.*

7A.2.a.iii. 1 0 Yes No Infant required reintubation - *If Yes, enter on Form 13A: AE, Q13A.19.* **DRAINT**

7A.2.b. Study drug dose/sham #1 tolerance, WITHIN <=24 HOURS AFTER DOSING PROCEDURE:

7A.2.b.i. 1 0 Yes No Severe PIE - *If yes, enter on Form 13A: AE, Q13A.5. and complete Form 21: SAE, Q21.4.* **DRAPIE**

7A.2.b.ii. 1 0 Yes No Severe Pulmonary Hemorrhage - *If Yes, enter on Form 13A: AE, Q13A.6. & complete Form 21: SAE, Q21.5.* **DRAPULM**

7A.2.b.iii. 1 0 Yes No Pneumothorax requiring chest tube - *If Yes, enter on Form 13A: AE, Q13A.7. & complete Form 21: SAE, Q21.6.* **DRAPNE**

FORM 7B: SUBSEQUENT STUDY DRUG DELIVERY

TOLSURF

DRBPAGEN Page of 4

Screening ID #	Secondary ID	Staff Initials	Randomization #
DRBLD	DRBACROS	DRBSTFID	DRBRANDN

7B.1. **STUDY DRUG DOSE/SHAM:** #2 #3 #4 #5 **DRBNUM**
 7B.1.a. Was this study drug dose/sham administered within **1 - 2 days after previous dose?** No Yes **DRBSDADMIN** Go to Q7B.1.b.

7B.1.a.i. **Primary reason this study drug dose/sham was not given within 1- 2 days after previous dose:** (select one/see MOP) **DRBDNG**

1 Discontinued study drug/sham → This form is complete.

2 Withdrew from study → Complete Form 20: Study Drug Discontinuation Form

3 Death → This form is complete. Complete Form 17: Death Report and Form 21: SAE, Q21.1.

4 Delayed - Infant extubated →

5 Delayed - clinical instability →

6 Delayed - weekend/holiday →

7 Study drug dosing error (see MOP) → Complete Form 19: Protocol Violations, Q19.2.e.

7B.1.a.ii. **Was this study drug/sham dose subsequently administered?** (Follow to DOL 35, see MOP)

Yes Go to Q7B.1.b. **DRBDSUBAD** No Proceed to Form 8

7B.1.b. Tracheal Aspirate obtained prior to this study drug dose/sham? Yes No **DRBTAO**

Month Day Year Time: (24h-clock) **DRBTAD** / **DRBTADH** **DRBTADM**

7B.1.c. Was there a problem with Tracheal Aspirate sampling? 1 Yes No **DRBTAPROB** (see MOP) Enter on Form 13A: Adverse Events, Q13A.20.

7B.1.d. Is infant currently receiving Inhaled Nitric Oxide? Yes No **DRBINOADM** **DRBINOCN**

7B.1.d.i. Concentration: PPM
 Complete Form 19: Protocol Violations, Q19.2.g.

7B.2 **STUDY DRUG/SHAM - DATE & TIME DOSE GIVEN:** **DRBSURD** / **DRBSURDH** **DRBSURDM** If possible, please avoid suctioning for at least 15 hrs after study drug/sham dosing procedure.

Time	Vent Mode	PIP/△P	PEEP	MAP	Fi O ₂	O ₂ Sat
0 (pre)	CMV or HFV					
1hr post						
2hr post						

7B.2.a. Study drug dose/sham tolerance, **WITHIN <=4 HOURS AFTER DOSING PROCEDURE:**

DRBRESP 7B.2.a.i. 1 Yes 0 No Severe respiratory decompensation (defined as increased RSS > 5 above baseline sustained > 24hr) - If Yes, enter on Form 13A: AE, Q13A.3. and complete Form 21: SAE, Q21.2.

DRBCPRGVN 7B.2.a.ii. 1 Yes 0 No Severe cardiopulmonary decompensation requiring CPR with chest compressions and cardiac meds - If Yes, enter on Form 13A: AE, Q13A.4. and complete Form 21: SAE, Q21.3.

DRBINT 7B.2.a.iii. 1 Yes 0 No Reintubation required during or ≤ 4 hrs of dosing - If Yes, enter on Form 13A: AE, Q13A.19.

7B.2.b. Study drug dose/sham tolerance, **WITHIN <=24 HOURS AFTER DOSING PROCEDURE:** **DRBPIE**

7B.2.b.i. 1 Yes 0 No Severe PIE - If Yes, enter on Form 13A: AE, Q13A.5. and complete Form 21: SAE, Q21.4. **DRBPULM**

7B.2.b.ii. 1 Yes 0 No Severe Pulmonary Hemorrhage - If Yes, enter on Form 13A: AE, Q13A.6. and complete Form 21: SAE, Q21.5

7B.2.b.iii. 1 Yes 0 No Pneumothorax with chest tube - If Yes, enter on Form 13A: AE, Q13A.7. and complete Form 21: SAE, Q21.6. **DRBPNE**

FORM 8: STUDY DAY 0 - 31 RESPIRATORY PARAMETERS

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #	Page #
PRBID	PRBACROS	PR2STFID	PRBRANDN	PRBPAGEN
PR2ID	PR2ACROS		PR2RANDN	PR2PAGEN

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Date of Study entry (mm/dd/yy): (fake field) (Study Day (SD) 00 Date = Date of Initial Study drug dose/sham found on Form 7A, Q7A.2)

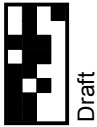
Complete these pages from Study Day 00 (SD00) through Study Day 31 (SD31).

Hour	Study day	Date (mm/dd/yy)	Time (24 hr)	PEEP/CPAP	MAP	Fi O ₂	NC Flow LPM	iNO ppm	Respiratory Status (code)*
<input type="text"/> hr	SD <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/> hr	SD <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/> hr	SD <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/> hr	SD <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/> hr	SD <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/> hr	SD <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/> hr	SD <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/> hr	SD <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/> hr	SD <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/> . <input type="text"/>	<input type="text"/>	<input type="text"/>

EACH LINE REPRESENTS ONE RECORD WHICH WILL INCLUDE BANNER INFO

PRBSDHR is a combo of the first 2 columns, and the data will look like this: 0801. The master table has added fields that are a subset of this field and they are PRBHR and PRBSD.

- * Respiratory Support Status:
- 1=CMV
 - 2=HFV
 - 3=NIMV (Nasal IMV, SiPAP, BiPAP)
 - 4=CPAP
 - 5=HFNC or NC > 2 lpm
 - 6=O2:NC (≤ 2 lpm or Oxyhood)
 - 7=Ext in RA, off all support



Draft

FORM 9A: STUDY DAY 32 - 120 RESPIRATORY PARAMETERS

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #	Page #
PRCID/ PRZID	PRCACROS/ PRZACROS		PRCRANDN/ PRZRANDN	PRCPAGEN/ PRZPAGEN

Draft



Date of Study Entry: (fake field) / /
Month Day Year

Complete these pages from SD32 through SD120, or until discharge to home or other hospital.

Study day	Date (mm/dd/yy)	Time (24 hr)	PEEP/CPAP	MAP	Fi O ₂	NC Flow LPM	iNO ppm	Respiratory Status (code)*
SD PRCSD	/ /	:			.	.		PRCRCODE
SD	PRCRDATE /	:			.	.		
SD	/ /	PRCTIMEH:			.	.		
SD	/ /	PRCTIMEM			.	.		
SD		:	PRCPEEP		.	.		
SD		:		PRCMAP	.	.		
SD TBLPRC	/ /	:			PRCFIO2	.		
SD						PRCNCF		
SD							PRCINO	

EACH LINE REPRESENTS ONE RECORD WHICH WILL INCLUDE BANNER INFO AND EXPORT INTO TBLPRC

Fields marked with PRC prefix export into PRCscratch1 table, Fields marked with PRZ prefix export into PRZscratch1 table (only data from page 10 goes into tblPRZ table)

Answer the question below ONLY if this is Form 9A, Page 10

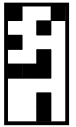
9A.1. Is infant in study hospital on Study Day 121? Yes No

Complete Form 9B: SD 121 - Discharge Respiratory Parameters, until infant is discharged or back transported.

9A.1.a. How many Form 9Bs have been completed for this infant? PRZARPCN

PRZHOSPLUS

- * Respiratory Support Status:
- 1=CMV
 - 2=HFV
 - 3=NIMV (Nasal IMV, SiPAP, BiPAP)
 - 4=CPAP
 - 5= HFNC or NC >2 lpm
 - 6=O₂:NC (≤ 2 lpm or Oxyhood)
 - 7=Ext in RA, off all support



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FORM 9B: STUDY DAY 121 - DISCHARGE RESPIRATORY PARAMETERS

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #	Additional Form 9B#s
ARPID: [][]	ARPCACROS: [][]	ARZSTFID: [][]	ARPRANDN: [][]	ARPADDN: [][]
ARZID: [][]	ARZACROS: [][]		ARZRANDN: [][]	ARZADDN: [][]

Enter a sequential # here for each Form 9B used for this infant, (e.g. 01, 02, 03, 04)

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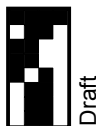
Date of Study Entry (mm/dd/yy): (fake field) [][] / [][] / [][] (Study Day (SD) 00 Date = Date of Initial Study drug dose/sham found on Form 7A, Q7A.2)
 Complete this form until infant is discharged from study hospital.

Study day	Date (mm/dd/yy)	Time (24 hr)	PEEP/CPAP	MAP	Fi O ₂	NC Flow LPM	iNO ppm	Respiratory Status (code)*
SD ARPSD	[][] / [][] / [][]	[][] : [][]	[][]	[][]	[][] . [][]	[][] . [][]	[][]	ARPRCODE
SD	ARPRDATE [][] / [][] / [][]	[][] : [][]	[][]	[][]	[][] . [][]	[][] . [][]	[][]	[][]
SD	[][] / [][] / [][]	ARPTIMEH [][]	[][]	[][]	[][] . [][]	[][] . [][]	[][]	[][]
SD	[][] / [][] / [][]	ARPTIMEM [][]	[][]	[][]	[][] . [][]	[][] . [][]	[][]	[][]
SD	[][] / [][] / [][]	[][] : [][]	ARPPEEP [][]	[][]	[][] . [][]	[][] . [][]	[][]	[][]
SD	[][] / [][] / [][]	[][] : [][]	[][]	ARPMAP [][]	[][] . [][]	[][] . [][]	[][]	[][]
SD	[][] / [][] / [][]	[][] : [][]	[][]	[][]	ARPFIO2 [][]	[][] . [][]	[][]	[][]
SD	[][] / [][] / [][]	[][] : [][]	[][]	[][]	[][] . [][]	ARPNCF [][]	[][]	[][]
SD	[][] / [][] / [][]	[][] : [][]	[][]	[][]	[][] . [][]	[][] . [][]	ARPINO [][]	[][]

Will another Form 9B: Study Day 121 - Discharge Respiratory Parameters be used for this infant?
FAKE FIELD Yes No

* Respiratory Support Status:
 1=CMV
 2=HFV
 3=NIMV (Nasal IMV, SiPAP, BiPAP)
 4=CPAP
 5= HFNC or NC >2 lpm
 6=O2:NC (<= 2 lpm or Oxyhood)
 7=Ext in RA, off all support

EACH LINE REPRESENTS ONE RECORD WHICH WILL INCLUDE BANNER INFO



Draft

FORM 10A: EXTUBATION DATA



Draft

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
EXTID	EXTSTFID EXTACROS		EXTRANDN

10.1 EXTUBATION (see MOP for instructions)

10.1.a. Was infant extubated? Yes No **EXTEXTUB**

10.1.a.i. Date initially extubated: / / Time: : **EXTEXH1** : **EXTEXM1**
Month Day Year 24 hour clock

10.2 WAS INFANT REINTUBATED? Yes No **EXTRINTUB**

10.3 RECORD OF REINTUBATION(S) (Do not include elective reintubations after self-extubation or ET tube changes)

10.3.a. Date reintubated: / / Time: : **EXTRH1** : **EXTREM1**
Month Day Year 24 hour clock

10.3.a.i. Reason reintubated: **EXTRREA1**

- Failed nasal CPAP (see MOP for definition)
- Recurrent apnea and bradycardia
- Surgery
- Other

10.3.a.ii. 2nd extubation date: / / Time: : **EXTEXH2** : **EXTEXM2**
Month Day Year 24 hour clock

10.3.b. Date reintubated: / / Time: : **EXTRH2** : **EXTREM2**
Month Day Year 24 hour clock

10.3.b.i. Reason reintubated: **EXTRREA2**

- Failed nasal CPAP (see MOP for definition)
- Recurrent apnea and bradycardia
- Surgery
- Other

10.3.b.ii. 3rd extubation date: / / Time: : **EXTEXH3** : **EXTEXM3**
Month Day Year 24 hour clock

10.3.c. Date reintubated: / / Time: : **EXTRH3** : **EXTREM3**
Month Day Year 24 hour clock

10.3.c.i. Reason reintubated: **EXTRREA3**

- Failed nasal CPAP (see MOP for definition)
- Recurrent apnea and bradycardia
- Surgery
- Other

10.3.c.ii. 4th extubation date: / / Time: : **EXTEXH4** : **EXTEXM4**
Month Day Year 24 hour clock

Use Form 10B: Additional Extubation Data to document additional extubations.

10A.4 Will additional extubations be documented on Form 10B: Additional Extubation Data?

Yes No **EXTADEXTFM**

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FORM 10B: ADDITIONAL EXTUBATION DATA

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
: EX2ID	EX2ACROS	EX2STFID	EX2RANDN

10B.1 Will additional extubations be reported below? Yes No → Form complete
EX2ADDEX

10B.2 RECORD OF REINTUBATION(S) (Do not include elective reintubations after self-extubation or ET tube changes)

10B.2.a. Date reintubated: [] / **EX2RED4** [] / [] **EX2REH4** Time: [] : [] **EX2REM4**
Month Day Year 24 hour clock

10B.2.a.i. Reason reintubated: **EX2RREA4**
 Failed nasal CPAP (see MOP for definition) Surgery
 Recurrent apnea and bradycardia Other

10B.2.a.ii. 5th extubation date: [] / **EX2EXD5** [] **EX2EXH5** Time: [] : [] **EX2EXM5**
Month Day Year 24 hour clock

10B.2.b. Date reintubated: [] / **EX2RED5** [] / [] **EX2REH5** Time: [] : [] **EX2REM5**
Month Day Year 24 hour clock

10B.2.b.i. Reason reintubated: **EX2RREA5**
 Failed nasal CPAP (see MOP for definition) Surgery
 Recurrent apnea and bradycardia Other

10B.2.b.ii. 6th extubation date: [] / **EX2EXD6** [] **EX2EXH6** Time: [] : [] **EX2EXM6**
Month Day Year 24 hour clock

10B.2.c. Date reintubated: [] / **EX2RED6** [] / [] **EX2REH6** Time: [] : [] **EX2REM6**
Month Day Year 24 hour clock

10B.2.c.i. Reason reintubated: **EX2RREA6**
 Failed nasal CPAP (see MOP for definition) Surgery
 Recurrent apnea and bradycardia Other

10B.2.c.ii. 7th extubation date: [] / **EX2EXD7** [] **EX2EXH7** Time: [] : [] **EX2EXM7**
Month Day Year 24 hour clock

10B.2.d. Date reintubated: [] / **EX2RED7** [] / [] **EX2REH7** Time: [] : [] **EX2REM7**
Month Day Year 24 hour clock

10B.2.d.i. Reason reintubated: **EX2RREA7**
 Failed nasal CPAP (see MOP for definition) Surgery
 Recurrent apnea and bradycardia Other

10B.2.d.ii. 8th extubation date: [] / **EX2EXD8** [] **EX2EXH8** Time: [] : [] **EX2EXM8**
Month Day Year 24 hour clock

Draft





Draft

FORM 11A: CO-MORBIDITIES OF PREMATURETY Dosing Period (Enrollment to 7 days after final dose)

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMMID	CMMACROS	CMMSTFID	CMMRANDN

11A.1. NEUROLOGIC: Dosing Period (Enrollment to 7 days after final dose)

11A.1.a. IVH:

11A.1.a.i. IVH: Yes No Unknown

11A.1.a.ii. How was IVH determined? MRI HUS CT Scan Unknown
(select all that apply)

11A.1.a.iii. IVH is new or worsened since Enrollment?

Yes No Unknown

Grade 1 or 2
 Unilateral Grade 3 - 4
 Bilateral Grade 3 - 4

Enter on Form 13A: Adverse Events, Q13A.8.

11A.1.b. Cystic PVL:

11A.1.b.i. Cystic PVL: Yes No Unknown

11A.1.b.ii. How was Cystic PVL determined? MRI HUS CT Scan Unknown
(select all that apply)

11A.1.b.iii. Cystic PVL is new or worsened since Enrollment?

Yes No Unknown

Enter on Form 13A: Adverse Events, Q13A.9.

11A.1.c. Hydrocephalus requiring shunt: Yes No Unknown

CMMHYD

Enter on Form 13A: Adverse Events, Q13A.10.

11A.2. GASTROINTESTINAL: Dosing Period (Enrollment to 7 days after final dose)

NEC is defined as: pneumotosis, hepato-biliary gas, or pneumoperitoneum AND with one or more of the following: bilious gastric aspirate or emesis, abdominal distension, or occult or gross blood in stool not from fissure.

11A.2.a. NEC (see MOP):

11A.2.a.i. NEC: (newly diagnosed since enrollment) Yes No Unknown

11A.2.a.ii. Date of diagnosis: / /
Month Day Year

11A.2.a.iii. Outcome:
 NEC with surgery (inc. peritoneal drain placement)
 NEC without surgery

11A.2.a.iv. Date of surgery: / /
Month Day Year

Enter on Form 14A: Hospital Course, Q14A.2.

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FORM 11A: CO-MORBIDITIES OF PREMATURITY
Dosing Period (Enrollment to 7 days after final dose)

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMNID	CMNSTFID	CMNACROS	CMNRANDN

11A.2.b. Isolated GI Perforation without NEC: (see MOP for definition)

11A.2.b.i. Isolated GI Perforation without NEC? **CMNGIP**
 1 Yes (laparotomy) 2 Yes (drain without laparotomy) 0 No 8 Unknown

Enter on Form 13A: Adverse Events, Q13A.12.

11A.2.b.ii. Date of diagnosis: **CMNGIPD**

/ /
 Month Day Year

Enter surgery date on Form 14A: Hospital Course, Q14A.2.

11A.3. PULMONARY: Dosing Period (Enrollment to 7 days after final dose)

11A.3.a. Severe Pulmonary Interstitial Emphysema (PIE): (see MOP for definition)

1 Yes → Enter on Form 13A: AEs, Q13A.5.
 0 No **CMNPIE**

11A.3.a.i. Date of diagnosis:

/ /
 Month Day Year **CMNPIED**

11A.3.b. Severe Pulmonary Hemorrhage: (see MOP for definition)

1 Yes → Enter on Form 13A: AEs, Q13A.6.
 0 No **CMNPUL**

11A.3.b.i. Date of diagnosis:

/ /
 Month Day Year **CMNPULD**

11A.3.c. Pneumothorax requiring chest tube:

1 Yes → Enter on Form 13A: AEs, Q13A.7.
 0 No **CMNPNE**

11A.3.c.i. Date of diagnosis:

/ /
 Month Day Year **CMNPNEED**

11A.3.d. Tracheomalacia:

1 Yes → Enter on Form 13A: AEs, Q13A.13.
 0 No **CMNMAL**

11A.3.d.i. Date of diagnosis:

/ /
 Month Day Year **CMNMALD**

11A.3.e. Tracheal stenosis:

1 Yes → Enter on Form 13A: AEs, Q13A.14.
 0 No **CMNSTE**

11A.3.e.i. Date of diagnosis:

/ /
 Month Day Year **CMNSTED**

11A.3.f. Vocal chord paralysis:

1 Yes → Enter on Form 13A: AEs, Q13A.29.
 0 No **CMNVOC**

11A.3.f.i. Date of diagnosis:

/ /
 Month Day Year **CMNVOCED**

Draft





Draft

FORM 11A: CO-MORBIDITIES OF PREMATURITY Dosing Period (Enrollment to 7 days after final dose)

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMO1D	CMOACROS	CMOSTFID	CMORANDN

11A.4. CARDIOVASCULAR: Dosing Period (Enrollment to 7 days after final dose)

11A.4.a. PDA requiring treatment: (see MOP)

Yes No Unknown **CMOPDA**

Enter on Form 13A: Adverse Events, Q13A.15.

Treatment: Enrollment to 7 days after final dose

11A.4.a.i. Treated with Indomethacin/Ibuprofen: Yes No Unknown **CMOINDIBU**

11A.4.a.ii. Ligation: Yes No Unknown **CMOLIG**

11A.4.a.iii. Date of surgery: **CMOLIGSURD** / / → Enter on Form 14A: Hospital Course, Q14A.2.

11A.4.b. Hypotension: (see MOP) **CMOHYP** Yes No Unknown

Treatment: Enrollment to 7 days after final dose

11A.4.b.i. Dopamine > 20 mc/kg/min > 24 hours

Yes **CMOHYPDOP**
 No
 Unknown

Note: If death occurred < 24h post pressor initiation, please mark "Yes" (see MOP).

Enter on Form 13A: Adverse Events, Q13A.16., if "Yes" is selected for either "Dopamine > 20 mc/kg/min > 24 hours" or "Two or more pressor agents > 24 hours".

11A.4.b.ii. Two or more pressor agents > 24 hours (includes hydrocortisone)

Yes **CMOHYPPR2**
 No
 Unknown

11A.4.c. Pulmonary Hypertension: (see MOP) Yes No Unknown **CMOPHY**

11A.4.c.i. How was diagnosis determined: (select all that apply) Clinical Echocardiogram Unknown **CMOPHYCLI** **CMOPHYECH** **CMOPHYUNK**

11A.4.c.ii. Date of diagnosis: **CMOPHYD** / / → Enter on Form 13A: Adverse Events, Q13A.17.

Draft



FORM 11A: CO-MORBIDITIES OF PREMATURITY
Dosing Period (Enrollment to 7 days after final dose)

Draft

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMPID	CMPACROS	CMPSTFID	CMPRANDN

11A.5. CULTURE PROVEN SEPSIS: Dosing Period (Enrollment to 7 days after final dose)

Record for blood, CSF, urine, or TA culture samples. Record the dates of each positive sample drawn for each episode of sepsis/infection that resulted in treatment with antibiotics, antifungals, or antivirals for ≥ 7 days.

11A.5.a. Did infant have culture proven sepsis? Yes No Unknown

Note: If infant was on abx and death due to sepsis occurred without a positive culture or abx given for < 7 days, please mark "Yes" (see MOP).

Enter on Form 13A: Adverse Events, Q13A.23.

Date specimen drawn: Month / Day / Year CMPSD1	Specimen type: (select one) <input checked="" type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input checked="" type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral CMPSPE1 CMPBAC1 CMPFUN1 1
Date specimen drawn: Month / Day / Year CMPSD2	Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral CMPSPE2 CMPBAC2 CMPFUN2 1
Date specimen drawn: Month / Day / Year CMPSD3	Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral CMPSPE3 CMPBAC3 CMPFUN3 1
Date specimen drawn: Month / Day / Year CMPSD4	Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral CMPSPE4 CMPBAC4 CMPFUN4 1
Date specimen drawn: Month / Day / Year CMPSD5	Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral CMPSPE5 CMPBAC5 CMPFUN5 1
Date specimen drawn: Month / Day / Year CMPSD6	Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral CMPSPE6 CMPBAC6 CMPFUN6 1
Date specimen drawn: Month / Day / Year CMPSD7	Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral CMPSPE7 CMPBAC7 CMPFUN7 1
Date specimen drawn: Month / Day / Year CMPSD8	Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral CMPSPE8 CMPBAC8 CMPFUN8 1
Date specimen drawn: Month / Day / Year CMPSD9	Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral CMPSPE9 CMPBAC9 CMPFUN9 1

Draft





FORM 11A: CO-MORBIDITIES OF PREMATURITY
Dosing Period (Enrollment to 7 days after final dose)

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMQID	CMQACROS	CMQSTFID	CMQRANDN

11A.5.b. Did infant have RSV pneumonia? **1** Yes **0** No **8** Unknown
CMQRSV

11A.5.b.i. Date first positive TA culture or DFA collected: **CMQRSVD**

/ /
 Month Day Year

Enter on Form 13A: Adverse Events, Q13A.28.

11A.6. OPHTHALMOLOGIC: Dosing Period (Enrollment to 7 days after final dose)

11A.6.a. Was ROP screening performed? **1** Yes **0** No **8** Unknown
CMQROP

11A.6.a.i. ROP Classification: (worst stage observed in either eye)

CMQROPCLAS **0** No ROP **1** Stage 1 **2** Stage 2 **3** Stage 3
4 Stage 4 **5** Stage 5 **8** Unknown **9** Not Applicable

If ROP Stage 1 - 5, enter Form 13A: Adverse event, Q11A.22.

11A.6.a.ii. Was ROP surgery performed? **1** Yes **0** No **8** Unknown
(laser, cryo, etc.) **CMQROPSUR**

11A.6.a.iii. Date of surgery: **CMQROPSURD**

/ /
 Month Day Year





Draft

FORM 11B: CO-MORBIDITIES OF PREMATURITY Discharge Period (8 days after final dose to Discharge)

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMUID	CMUACROS	CMUSTFID	CMURANDN

11B.1. INFANT IN STUDY HOSPITAL AFTER DOSING PERIOD + 1 DAY?

CMUHOSP

Yes 1

No 0

Form 11B is complete. Proceed to Form 12A

Unknown 8

11B.2. NEUROLOGIC: Discharge Period (8 days after final dose to Discharge)

11B.2.a. IVH: 1 Yes 0 No 8 Unknown CMUIVH

11B.2.a.i. How was IVH determined? 1 MRI 1 CT Scan 1 HUS 1 Unknown
(select all that apply) CMUIVHMRI CMUIVHHUS (No MRI / CT Scan/HUS done) CMUIVHCTS CMUIVHUNK

11B.2.a.ii. IVH is new or worsened since Dosing Period?

CMUIVHNW 1 Yes 0 No 8 Unknown

1 Grade 1 or 2
 2 Unilateral Grade 3 - 4
 3 Bilateral Grade 3 - 4

Enter on Form 13B: CMUIVHGRD
Adverse Events, Q13B.7.

11B.2.b. Cystic PVL: 1 Yes 0 No 8 Unknown CMUPVL

11B.2.b. i. How was Cystic PVL determined? 1 MRI 1 CT Scan 1 HUS 1 Unknown
(select all that apply) CMUPVLMRI CMUPVLHUS (No MRI / CT Scan/HUS done) CMUPVLCTS CMUPVLUNK

11B.2.b.ii. Cystic PVL is new or worsened since Dosing Period?

CMUPVLNW 1 Yes 0 No 8 Unknown

Enter on Form 13B: Adverse Events, Q13B.8.

11B.2.c. Hydrocephalus requiring shunt: 1 Yes 0 No 8 Unknown

CMUHYD

Enter on Form 13B: Adverse Events, Q13B.9.

11B.3. GASTROINTESTINAL: Discharge Period (8 days after final dose to Discharge)

NEC is defined as: pneumatosis, hepato-biliary gas, or pneumoperitoneum AND with one or more of the following: bilious gastric aspirate or emesis, abdominal distension, or occult or gross blood in stool not from fissure.

11B.3.a. NEC: (see MOP) CMUNEC

11B.3.a.i. NEC (newly diagnosed since Dosing Period): 1 Yes 0 No 8 Unknown

11B.3.a.ii. Date of diagnosis: CMUNECD / /
Month Day Year
Enter on Form 13B: Adverse Events, Q13B.10.

CMUNECTYPE

11B.3.a.iii. Outcome:
 1 NEC with surgery (inc. peritoneal drain placement)
 2 NEC without surgery

11B.3.a.iv. Date of surgery: CMUNECSTURD / /
Month Day Year

Enter on Form 14A, Hospital Course, Q14A.2.

Draft





Draft

FORM 11B: CO-MORBIDITIES OF PREMATURITY Discharge Period (8 days after final dose to Discharge)

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMVID	CMVACROS	CMVSTFID	CMVRANDN

11B.3.b. Isolated GI Perforation without NEC: (see MOP for definition)

11B.3.b.i. Isolated GI Perforation without NEC?

CMVGIP

1 Yes (laparotomy) 2 Yes (drain without laparotomy) 0 No 8 Unknown

11B.3.b.ii. Date of diagnosis:

/ /
 Month Day Year

CMVGIPD

Enter surgery date on Form 14A: Hospital Course, Q14A.2. and Enter on Form 13B: Adverse Events, Q13B.11.

11B.4. PULMONARY: Discharge Period (8 days after final dose to Discharge)

11B.4.a. Severe Pulmonary Interstitial Emphysema (PIE):

CMVPIE

(see MOP for definition)

1 Yes

Enter on Form 13B: AEs, Q13B.4.

0 No

11B.4.a.i. Date of diagnosis:

/ /
 Month Day Year

11B.4.b. Severe Pulmonary Hemorrhage: (see MOP for definition)

1 Yes

Enter on Form 13B: AEs, Q13B.5.

0 No

CMVPUL

11B.4.b.ii. Date of diagnosis:

/ /
 Month Day Year

11B.4.c. Pneumothorax requiring new or additional chest tubes:

1 Yes

Enter on Form 13B: AEs, Q13B.6.

0 No

CMVPNE

11B.4.c.ii. Date of diagnosis:

/ /
 Month Day Year

11B.4.d. Tracheomalacia:

CMVMAL

1 Yes

Enter on Form 13B: AEs, Q13B.12.

0 No

11B.4.d.i. Date of diagnosis:

/ /
 Month Day Year

11B.4.e. Tracheal stenosis:

CMVSTE

1 Yes

Enter on Form 13B: AEs, Q13B.13.

0 No

11B.4.e.i. Date of diagnosis:

/ /
 Month Day Year

11B.4.f. Vocal chord paralysis:

CMVVOC

1 Yes

Enter on Form 13B: AEs, Q13B.25.

0 No

11B.4.f.i. Date of diagnosis:

/ /
 Month Day Year

Draft





Draft

FORM 11B: CO-MORBIDITIES OF PREMATURITY Discharge Period (8 days after final dose to Discharge)

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMWID	CMWACROS	CMWSTFID	CMWRANDN

11B.5. CARDIOVASCULAR: Discharge Period (8 days after final dose to Discharge)

11B5.a. PDA requiring treatment: (see MOP) **CMWPDA**

1 Yes 0 No 8 Unknown

Enter on Form 13B: Adverse Events, Q13B.14

Treatment: Discharge Period (8 days after final dose to Discharge) **CMWINDIBU**

11B.5.a.i. Treated with Indomethacin/Ibuprofen: 1 Yes 0 No 8 Unknown

11B.5.a.ii. Ligation: 1 Yes 0 No 8 Unknown **CMWLGIG**

11B.5.a.iii. Date of surgery: **CMWLIGSURD** / / → Enter on Form 14A: Hospital Course, Q14A.2.
Month Day Year

11B.5.b. Hypotension: (see MOP) **CMWHYP** 1 Yes 0 No 8 Unknown

Treatment: Discharge Period (8 days after final dose to Discharge)

11B.5.b.i. Dopamine > 20 mc/kg/min > 24 hours

1 Yes **CMWHYPDOP**
0 No
8 Unknown

11B.5.b.ii. Two or more pressor agents > 24 hours (includes hydrocortisone)

1 Yes **CMWHYPPR2**
0 No
8 Unknown

Note: If death occurred < 24h post pressor initiation, please mark "Yes" (see MOP).

Enter on Form 13B: Adverse Events, Q13B.15., if "Yes" is selected for either "Dopamine > 20 mc/kg/min > 24 hours" or "Two or more pressor agents > 24 hours".

11B.5.c. Pulmonary Hypertension: (see MOP) **CMWPHY** 1 Yes 0 No 8 Unknown

11B.5.c.i. How was diagnosis determined: (select all that apply) 1 Clinical **CMWPHYCLI** 1 Echocardiogram **CMWPHYECH** 1 Unknown **CMWPHYUNK**

11B.5.c.ii. Date of diagnosis: **CMWPHYD** / / → Enter on Form 13B: Adverse Events, Q13B.16.
Month Day Year

Draft





FORM 11B: CO-MORBIDITIES OF PREMATURITY
Discharge Period (8 days after final dose to Discharge)

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMXID	CMXACROS	CMXSTFID	CMXRANDN

11B.6. OPHTHALMOLOGIC: Discharge Period (8 days after final dose to Discharge)

11B.6.a. Was ROP screening performed? Yes No Unknown

11B.6.a.i. ROP Classification: (worst stage observed in either eye) **CMXROPCLAS**
 No ROP Stage 1 Stage 2 Stage 3
 Stage 4 Stage 5 Unknown Not Applicable

If ROP Stage 1 - 5, enter on Form 13B: Adverse Events, Q13B.18.

11B.6.a.ii. Was ROP surgery performed? (laser, cryo, etc.) Yes No Unknown
CMXROPSUR

11B.6.a.iii. Date of surgery: / / **CMXROPSURD**
Year Day Year

11B.7. CULTURE PROVEN SEPSIS: Discharge Period (8 days after final dose to Discharge)

Record for blood, CSF, urine, or TA culture samples. Record the dates of each positive sample drawn for each episode of sepsis/infection that resulted in treatment with antibiotics, antifungals, or antivirals for ≥ 7 days. **CMXSEP**

11B.7.a. Did infant have culture proven sepsis? Yes No Unknown

Note: If infant was on abx and death due to sepsis occurred without a positive culture or abx given for < 7 days, please mark "Yes" (see MOP).

Enter on Form 13B: Adverse Events, Q13B.19.

Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small>	CMXSPE1 Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral
Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small>	CMXSPE2 Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral
Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small>	CMXSPE3 Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral
Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small>	CMXSPE4 Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral
Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small>	CMXSPE5 Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral
Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small>	CMXSPE6 Specimen type: (select one) <input type="radio"/> blood <input type="radio"/> CSF <input type="radio"/> Urine <input type="radio"/> TA Organism: (select all that apply) <input type="radio"/> Bacterial <input type="radio"/> Fungal <input type="radio"/> Viral

Draft



FORM 11B: CO-MORBIDITIES OF PREMATURITY
Discharge Period (8 days after final dose to Discharge)

Draft

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
CMYID	CMYACROS	CMYSTFID	CMYRANDN

(continued from previous page) Record additional episodes of sepsis below.

<p>Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small></p>	<p>CMYSPE1 Specimen type: (select one) ¹ <input type="radio"/> blood ² <input type="radio"/> CSF ³ <input type="radio"/> Urine ⁴ <input type="radio"/> TA Organism: (select all that apply) ¹ <input type="radio"/> Bacterial ¹ <input type="radio"/> Fungal ¹ <input type="radio"/> Viral</p>
<p>Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small></p>	<p>CMYSPE2 Specimen type: (select one) ¹ <input type="radio"/> blood ² <input type="radio"/> CSF ³ <input type="radio"/> Urine ⁴ <input type="radio"/> TA Organism: (select all that apply) ¹ <input type="radio"/> Bacterial ¹ <input type="radio"/> Fungal ¹ <input type="radio"/> Viral</p>
<p>Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small></p>	<p>CMYSPE3 Specimen type: (select one) ¹ <input type="radio"/> blood ² <input type="radio"/> CSF ³ <input type="radio"/> Urine ⁴ <input type="radio"/> TA Organism: (select all that apply) ¹ <input type="radio"/> Bacterial ¹ <input type="radio"/> Fungal ¹ <input type="radio"/> Viral</p>
<p>Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small></p>	<p>CMYSPE4 Specimen type: (select one) ¹ <input type="radio"/> blood ² <input type="radio"/> CSF ³ <input type="radio"/> Urine ⁴ <input type="radio"/> TA Organism: (select all that apply) ¹ <input type="radio"/> Bacterial ¹ <input type="radio"/> Fungal ¹ <input type="radio"/> Viral</p>
<p>Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small></p>	<p>CMYSPE5 Specimen type: (select one) ¹ <input type="radio"/> blood ² <input type="radio"/> CSF ³ <input type="radio"/> Urine ⁴ <input type="radio"/> TA Organism: (select all that apply) ¹ <input type="radio"/> Bacterial ¹ <input type="radio"/> Fungal ¹ <input type="radio"/> Viral</p>
<p>Date specimen drawn: <input type="text"/> / <input type="text"/> / <input type="text"/> <small>Month Day Year</small></p>	<p>CMYSPE6 Specimen type: (select one) ¹ <input type="radio"/> blood ² <input type="radio"/> CSF ³ <input type="radio"/> Urine ⁴ <input type="radio"/> TA Organism: (select all that apply) ¹ <input type="radio"/> Bacterial ¹ <input type="radio"/> Fungal ¹ <input type="radio"/> Viral</p>

11B.8.b. Did infant have RSV pneumonia?

CMYRSV

¹ Yes ⁰ No ⁸ Unknown

11B.8.b.i. Date first positive
TA culture or
DFA collected:

/ /
Month Day Year

CMYRSVD

Enter on Form 13B:
Adverse Events, Q13B.24.





FORM 12A: BPD OUTCOMES - 36 WEEKS PMA

Draft

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
BP1ID	BP1ACROS	BP1STFID	BP1RANDN

36 Weeks PMA
BP1PMAWK

12A.1. Date, Weight, SpO2 and PCO2 at 36 weeks PMA:

Date: / / (Month/Day/Year)

Weight: grams

Oxygen Saturation: %

Most recent PCO2 prior to 36 week date: mm/Hg

12A.2. INFANT STATUS WHEN 36 Weeks PMA (± 1 week): (select one) BP1STAT36

Home
 Still in study hospital
 Transferred to other facility
 Dead

12A.2.a. Respiratory Status when 36 Weeks PMA (± 1 week): (select one)

Off ventilator, off CPAP, off oxygen, off nasal cannula (No BPD, go to Q12A.3.ii.)
 On mechanical ventilation (Yes BPD, go to Q12A.3.i.) **BP1VENT**
 On SiPAP, BiPAP or nasal prong ventilation (Yes BPD, go to Q12A.3.i.)
 On nasal CPAP (includes NC > 4 lpm in room air) (Yes BPD, go to Q12A.3.i.)
 On continuous nasal cannula > 2 lpm on any oxygen. (Yes BPD, go to Q12A.3.i.)
 On continuous nasal cannula (≤ 2 lpm in oxygen or ≤ 4 lpm in room air).

Unknown **8**
 Go to Q12A.3.iii.

Complete Form 17: Death Report

12A.2.a.i. FiO2: LPM: / Effective oxygen: FiO2: **BP1EFUNK**

Unknown
 0.30 **BP1EO30**

12A.2.a.ii Is effective oxygen ≤ 0.30? Yes No Go to Q12A.3.i.

Complete Oxygen Reduction Challenge Test when 36 Weeks PMA (± 1 week)

12A.2.a.iii Was an Oxygen Reduction Challenge Test completed when 36 weeks PMA (± 1 week)?

Yes **BP1OXC**
 No **0**
 Unknown **8** Go to Q12A.3.iii.

12A.2.a.iv. Challenge test date:

12A.2.a.v. Challenge test results:

Passed (Go to Q12A.3.ii) **BP1OXCHR**
 Failed (Go to Q12A.3.i) **0**

12A.2.a.vi. Reason challenge test not done: (see MOP)

Not eligible for challenge test
 Infant at non-study facility **BP1OXCNR**
 Infant discharged home
 Eligible (in study hospital), but not done

Enter on Form 18: Protocol Deviation, Q18.2.a. and Go to Q12A.3.i.

12A.3. BPD STATUS WHEN 36 WEEKS PMA (± 1 week) FOR SURVIVORS: (select one)

12A.3.i. Yes BPD **BP1SURV**

Select one: **BP1YBPDR**

Infant on nasal CPAP or ventilator or > 0.30 effective oxygen
 Infant failed Oxygen Reduction Challenge Test (or challenge not performed)
 Infant discharged or transferred ≤ 36 weeks and remains on continuous respiratory support (respiratory status codes 1 - 6)

12A.3.ii. No BPD **0**

Select one: **BP1NBPDR**

Infant off continuous respiratory support
 Infant passed Oxygen Reduction Challenge Test

12A.3.iii. Unknown **8**

12A.4. BPD STATUS WHEN 36 Weeks PMA, HAS BEEN REVIEWED BY PI **BP1PIR**

PI Signature: _____ PI signed form? Yes No PI Initials:

1 BP1PISD

BP1PIS

Draft



FORM 12B: BPD OUTCOMES - 40 WEEKS PMA

Draft

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
BP2ID	BP2ACROS	BP2STFID	BP2RANDN

BP2PMAWK

1 ● 40 Weeks PMA

12B.1. Date, Weight, SpO2 and PCO2 at 40 weeks PMA:

12.B.1.a Date:

BP2PMAD / / /
Month Day Year

12.B.1.b. Weight:

grams
 BP2PMAWT

12.B.1.c. Oxygen Saturation:

%
 BP2OXY5

12.B.1.d. Most recent PCO2 prior to 40 week date:

BP2PCO2 mm/Hg

12B.2. INFANT STATUS WHEN 40 Weeks PMA (± 1 week): (select one) BP2STAT40

3 Home 1 Still in study hospital 2 Transferred to other facility 0 Dead

12B.2.a. Did infant have BPD when 36 Weeks PMA?

BP2PDAT36 1 Yes 0 No 8 Unknown

Go to Q12B.2.b.

Go to Q12B.3.ii.

Go to Q12B.3.iii.

Complete Form 17: Death Report

12B.2.b. Respiratory Status when 40 Weeks PMA (± 1 week): (select one) BP2VENT

- 0 Off ventilator, off CPAP, off oxygen, off nasal cannula (No BPD, go to Q12B.3.ii.)
- 1 On mechanical ventilation (Yes BPD, go to Q12B.3.i.)
- 2 On SiPAP, BiPAP or nasal prong ventilation (Yes BPD, go to Q12B.3.i.)
- 3 On nasal CPAP (includes NC > 4 lpm in room air) (Yes BPD, go to Q12B.3.i.)
- 5 On continuous nasal cannula > 2 lpm on any oxygen.
- 4 On continuous nasal cannula (≤ 2 lpm in oxygen or ≤ 4 lpm in room air).
- 8 Unknown

Go to Q12B.3.iii.

12B.2.b.i. FiO₂: BP2FIO LPM: BP2LPM / Effective oxygen: FiO₂: BP2EFIO BP2EFUNK Unknown

12B.2.b.ii. Is effective oxygen ≤ 0.30? Yes 1 No 0 → Go to Q12B.3.i.

BP2EO30

Complete Oxygen Reduction Challenge Test when 40 Weeks PMA (± 1 week)

12B.2.b.iii. Was Oxygen Reduction Challenge Test completed when 40 weeks PMA (± 1 week)?

BP2OXC Yes 1 No 0 Unknown 8 → Go to Q12B.3.iii.

12B.2.b.iv. Challenge test date:

BP2OXCHD / /
Month Day Year

12B.2.b.v. Challenge test results:

1 Passed (Go to Q12B.3.ii)
 BP2OXCHR
 0 Failed (Go to Q12B.3.i)

12B.2.b.vi. Reason challenge test not done:(see MOP)

- 0 Not eligible for challenge test
- 1 Infant at non-study facility
- 2 Infant discharged home
- 3 Eligible (in study hospital), but not done

Enter on Form 18: Protocol Deviation, Q18.2.g. and Go to Q12B.3.i.

Draft





Draft

FORM 12B: BPD OUTCOMES - 40 WEEKS PMA

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
BP3ID	BP3ACROS	BP3STFID	BP3RANDN

BP3PMAWK

● 40 Weeks PMA
1

12B.3. BPD STATUS WHEN 40 WEEKS PMA (± 1 week) FOR Survivors: (select one)

12B.3.i.

Yes BPD

BP3SURV

(Select one below)

BP3YBPDR

- 1 Infant on nasal CPAP or ventilator or > 0.30 effective oxygen
- 2 Infant failed Oxygen reduction Challenge Test (or challenge not performed)
- 3 Infant now discharged or transferred ≤ 40 weeks and remains on continuous respiratory support (respiratory status codes 1 - 6)

12B.3.ii.

No BPD

(Select one below)

BP3NBPDR

- 4 Infant off continuous respiratory support
- 5 Infant passed Oxygen Reduction Challenge Test
- 6 Infant had no BPD at 36 weeks PMA

12B.3.iii.

Unknown

BP3

12B.4 BPD STATUS WHEN 40 WEEKS PMA, HAS BEEN REVIEWED BY

BP3PIR PRINCIPAL INVESTIGATOR

BP3PIS

PI Signature: _____ PI signed form? Yes No

PI Initials:

BP3PII

1 **BP3PISD**



TOLSURF FORM 13A: ADVERSE EVENTS

Dosing Period (Enrollment to 7 days after final dose)

Screening ID #	Secondary ID	Staff Initials	Randomization #
EZ1ID	EZ1ACROS	EZ1STFID	EZ1RANDN

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13A.1. Did any co-morbidities reported on Form 11A or adverse events occur during the Dosing Period?
 Yes No Unknown
 If "Yes", document below. PI must sign & date Form 13A, page 6. (See MOP)

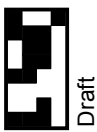
TIME POINT:
 Dosing Period
 39 EZ1VISIT

13A.2. Death **EZ1DEA**
 13A.2.a. Death occurred \leq 7 days after study drug dose/sham?
 Yes Complete Form 17: Death Report AND Form 21: Serious Adverse Events, Q21.1.
EZ1DEAOC
 No Complete Form 17: Death Report

Adverse Events If occurrence is "Yes" below, then report event on Form 21: SAE.	Date of Event (mm/dd/yy)	Severity	Relationship to Study Drug	Actions Taken	Outcome	Causality	Event Type
--	-----------------------------	----------	----------------------------	---------------	---------	-----------	------------

13A.3. Severe Respiratory Decompensation, defined as RSS > 5 above baseline for > 24 hrs.
EZ1RES
 13A.3.a. Occured \leq 4 hrs after dosing procedure?
 Yes No
EZ1RESOC
 13A.3.a.i. Enter on Form 21, SAE, Q21.2., and record SAE Form # here: **EZ1RESSAEN**
 This is not a reportable Adverse Event

13A.4. Severe Cardiopulmonary Decompensation, requiring CPR with chest compressions & cardiac meds.
EZ1CPR
 13A.4.a. Occured \leq 4 hrs after dosing procedure?
 Yes No
EZ1CPRC
 13A.4.a.i. Enter on Form 21, SAE, Q21.3., and record SAE Form # here: **EZ1CPRSAEN**
EZ1CPRD / **EZ1CPRR** / **EZ1CPRC**
EZ1CPRS / **EZ1CPRA** / **EZ1CPRC**



All 6 pages of Form 13A must be faxed to DCC and Principal Investigator must sign and date Form 13A, page 6.

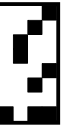
CODES FOR SEVERITY, RELATIONSHIP TO STUDY DRUG, ACTION TAKE, OUTCOME, CAUSALITY, AND EVENT TYPE ARE LOCATED AT THE BOTTOM OF PAGE 3.

TOLSURF FORM 13A: ADVERSE EVENTS

Dosing Period (Enrollment to 7 days after final dose)

Screening ID #	Secondary ID	Staff Initials	Randomization #
EZ2ID	EZ2ACROS	EZ2STFID	EZ2RANDN

Draft



TIME POINT: Dosing Period
 39
EZ2VISIT

Adverse Events If occurrence is "Yes" below, then report event on Form 21: SAE.	Date of Event (mm/dd/yy)	Severity	Relationship to Study Drug	Actions Taken	Outcome	Causality	Event Type
13A.5. <input checked="" type="radio"/> Severe PIE EZ2PIE ↓ 13A.5.a. Occured ≤ 24 hrs after dosing procedure? EZ2PIEOC Yes <input checked="" type="radio"/> No <input type="radio"/>	EZ2PIED		EZ2PIER		EZ2PIEO		EZ2PIET
13A.5.a.i. Enter on Form 21: SAE, Q21.4., and record SAE Form # here: <input type="text"/>				EZ2PIEA		EZ2PIEC	
13A.6. <input checked="" type="radio"/> Severe Pulmonary Hemorrhage EZ2PUL ↓ 13A.6.a. Occured ≤ 24 hrs after dosing procedure? EZ2PULOC Yes <input checked="" type="radio"/> No <input type="radio"/>	EZ2PULD		EZ2PULR		EZ2PULO		EZ2PULT
13A.6.a.i. Enter on Form 21: SAE, Q21.5., and record SAE Form # here: <input type="text"/>				EZ2PULA		EZ2PULC	
13A.7. <input checked="" type="radio"/> Pneumothorax requiring chest tube EZ2PNE ↓ 13A.7.a. Occured ≤ 24 hrs after dosing procedure? EZ2PNEOC Yes <input checked="" type="radio"/> No <input type="radio"/>	EZ2PNED		EZ2PNER		EZ2PNEO		EZ2PNET
13A.7.a.i. Enter on Form 21: SAE, Q21.6., and record SAE Form # here: <input type="text"/>				EZ2PNEA		EZ2PNEC	

CODES FOR SEVERITY, RELATIONSHIP TO STUDY DRUG, ACTION TAKE, OUTCOME, CAUSALITY, AND EVENT TYPE ARE LOCATED AT THE BOTTOM OF PAGE 3.

Draft

All 6 pages of Form 13A must be faxed to DCC and Principal Investigator must sign and date Form 13A, page 6.

TOLSURF FORM 13A: ADVERSE EVENTS

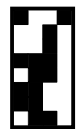
Dosing Period (Enrollment to 7 days after final dose)

Screening ID #	Secondary ID	Staff Initials	Randomization #
EZ3ID	EZ3ACROS	EZ3STFID	EZ3RANDN

Draft

EZ3VISIT 39 ● Dosing Period

Adverse Events	Date of Event (mm/dd/yy)	Severity	Relationship to Study Drug	Actions Taken	Outcome	Causality	Event Type
13A.8. 1 ○ IVH EZ3IVH	EZ3IVHD /	EZ3IVHS	EZ3IVHR	EZ3IVHA	EZ3IVHO	EZ3IVHC	EZ3IVHT
13A.9. 1 ○ Cystic PVL EZ3PVL	EZ3PVLD /	EZ3PVLS	EZ3PVLR	EZ3PVLA	EZ3PVLO	EZ3PVLC	EZ3PVLT
13A.10. 1 ○ Hydrocephalus requiring shunt EZ3HYD	EZ3HYDD /	EZ3HYDS	EZ3HYDR	EZ3HYDA	EZ3HYDO	EZ3HYDC	EZ3HYDT
13A.11. 1 ○ NEC EZ3NEC	EZ3NECD /	EZ3NECS	EZ3NECR	EZ3NECA	EZ3NECO	EZ3NECC	EZ3NECT
13A.12. 1 ○ Isolated GI Perforation EZ3GIP	EZ3GIPD /	EZ3GIPS	EZ3GIPR	EZ3GIPA	EZ3GIPO	EZ3GIPC	EZ3GIPT
13A.13. 1 ○ Tracheomalacia EZ3MAL	EZ3MALD /	EZ3MALS	EZ3MALR	EZ3MALA	EZ3MALO	EZ3MALC	EZ3MALT
13A.14. 1 ○ Tracheal Stenosis EZ3STE	EZ3STED /	EZ3STES	EZ3STER	EZ3STEA	EZ3STEO	EZ3STEC	EZ3STET
13A.15. 1 ○ PDA requiring treatment EZ3PDA	EZ3PDAD /	EZ3PDAS	EZ3PDAR	EZ3PDAA	EZ3PDAO	EZ3PDAC	EZ3PDAT
13A.16. 1 ○ Hypotension (when treated as reported on Q11A.4.b.) EZ3HYP	EZ3HYPD /	EZ3HYPS	EZ3HYPR	EZ3HYPA	EZ3HYPO	EZ3HYPC	EZ3HYPT
13A.17. 1 ○ Pulmonary Hypertension EZ3PHY	EZ3PHYD /	EZ3PHYS	EZ3PHYR	EZ3PHYA	EZ3PHYO	EZ3PHYC	EZ3PHYT



Draft

All 6 pages of Form 13A must be faxed to DCC and Principal Investigator must sign and date Form 13A, page 6.

1=Mild 2=Moderate 3=Severe 4=Life-threatening 8=Unavailable/unknown (see MOP)	1=Not related 2=Unlikely 3=Possible 4=Probably 5=Definitely related 8=Unavailable/Unknown	1=Not applicable 2=Study drug Discontinued 3=Standard care 8=Unavailable/Unknown	1=Recovered/Resolved 2=Improved 3=Unchanged 4=Worsened 5=Death=SAE 8=Unavailable/Unknown	1=Not rel. to study drug 2=Concomitant med 3=Underlying condition 4=Study drug dosing 5=Unknown 6=Other	1=Expected 2=Unexpected
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TOLSURF FORM 13: ADVERSE EVENTS

Dosing Period (Enrollment to 7 days after final dose)

Screening ID #	Secondary ID	Staff Initials	Randomization #
EZ4ID	EZ4ACROS	EZ4STFID	EZ4RANDN

EZ4VISIT ● Dosing Period 39

Adverse Events	Date of Event (mm/dd/yy)	Severity	Relationship to Study Drug	Actions Taken	Outcome	Causality	Type of Event
13A.18. <input type="radio"/> 1 Prolonged bradycardia/desaturation within 4 hours of dosing EZ4PBD	EZ4PBDD /		EZ4PBDR		EZ4PBDO		EZ4PBDT
		EZ4PBDS		EZ4PBDA		EZ4PBDC	
13A.19. <input type="radio"/> 1 Endotracheal tube problems requiring reintubation w/in 4hr of dosing EZ4ETP	EZ4ETPD /		EZ4ETPR		EZ4ETPO		EZ4ETPT
		EZ4ETPS		EZ4ETPA		EZ4ETPC	
13A.20. <input type="radio"/> 1 Problems obtaining Tracheal Aspirate samples EZ4PTA	EZ4PTAD /		EZ4PTAR		EZ4PTAO		EZ4PTAT
		EZ4PTAS		EZ4PTAA		EZ4PTAC	
13A.21. <input type="radio"/> 1 Unexpected Adverse Event EZ4UNXAE	EZ4UNXAE /		EZ4UNXAER		EZ4UNXAE0		EZ4UNXAET
13A.21.a. This AE is related to and occurred within, 7 days of study drug administration. 1 <input type="radio"/> Yes 0 <input type="radio"/> No EZ4UNXAESD	Describe AE below:		EZ4UNXAES		EZ4UNXAEA		EZ4UNXAEC
EZ4UNXAECM							
Complete SAE Form, Q21.7. and record SAE Form # here:			EZ4UNXAENO				
13A.22. <input type="radio"/> 1 ROP EZ4ROP	EZ4ROPD /		EZ4ROPR		EZ4ROPO		EZ4ROPT
		EZ4ROPS		EZ4ROPA		EZ4ROPC	
13A.23. <input type="radio"/> 1 Sepsis EZ4SP1	EZ4SP1D /		EZ4SP1R		EZ4SP10		EZ4SP1T
		EZ4SP1S		EZ4SP1A		EZ4SP1C	

All 6 pages of Form 13A must be faxed to DCC and Principal Investigator must sign and date Form 13A, page 6.

1=Mild 2=Moderate 3=Severe 4=Life-threatening 8=Unavailable/Unknown (see MOP)	1=Not related 2=Unlikely 3=Possible 4=Probably 5=Definitely related 8=Unavailable/Unknown	1=Not applicable 2=Study drug Discontinued 3=Standard care 8=Unavailable/Unknown	1=Recovered/Resolved 2=Improved 3=Unchanged 4=Worsened 5=Death=SAE 8=Unavailable/Unknown	1=Not rel. to study drug 2=Concomitant med 3=Underlying condition 4=Study drug dosing 5=Unknown 6=Other	1=Expected 2=Unexpected
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Draft



Draft

Dosing Period (Enrollment to 7 days after final dose)

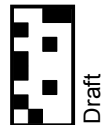
Screening ID #	Secondary ID	Staff Initials	Randomization #
EZ5ID	EZ5ACROS	EZ5STFID	EZ5RANDN

Draft

EZ5VISIT 39 ● Dosing Period

Adverse Events	Date of Event (mm/dd/yy)	Severity	Relationship to Study Drug	Actions Taken	Outcome	Causality	Event Type
13A.24. EZ5SP1 1 <input type="radio"/> Sepsis	EZ5SP1D / /	EZ5SP1S	EZ5SP1R	EZ5SP1A	EZ5SP1O	EZ5SP1C	EZ5SP1T
13A.25. EZ5SP2 1 <input type="radio"/> Sepsis	EZ5SP2D / /	EZ5SP2S	EZ5SP2R	EZ5SP2A	EZ5SP2O	EZ5SP2C	EZ5SP2T
13A.26. EZ5SP3 1 <input type="radio"/> Sepsis	EZ5SP3D / /	EZ5SP3S	EZ5SP3R	EZ5SP3A	EZ5SP3O	EZ5SP3C	EZ5SP3T
13A.27. EZ5SP4 1 <input type="radio"/> Sepsis	EZ5SP4D / /	EZ5SP4S	EZ5SP4R	EZ5SP4A	EZ5SP4O	EZ5SP4C	EZ5SP4T
EZ5RSV 13A.28. 1 <input type="radio"/> RSV Pneumonia	EZ5RSVD / /	EZ5RSVS	EZ5RSVR	EZ5RSVA	EZ5RSVO	EZ5RSVC	EZ5RSVT
EZ5VCP 13A.29. 1 <input type="radio"/> Vocal chord paralysis	EZ5VCPD / /	EZ5VCP S	EZ5VCP R	EZ5VCP A	EZ5VCP O	EZ5VCP C	EZ5VCP T
EZ5OTH1 13A.30. <input type="radio"/> Other 1 Describe "Other" event below:	EZ5OTH1D / /	EZ5OTH1S	EZ5OTH1R	EZ5OTH1A	EZ5OTH1O	EZ5OTH1C	EZ5OTH1T
EZ5OTH1CM							

1=Mild 2=Moderate 3=Severe 4=Life-threat ening 8=Unavailable/ Unknown (see MOP)	1=Not related 2=Unlikely 3=Possible 4=Probably 5=Definitely related 8=Unavailable/ Unknown	1=Not applicable 2=Study drug Discontinued 3=Standard care 8=Unavailable/ Unknown	1=Recovered/ Resolved 2=Improved 3=Unchanged 4=Worsened 5=Death=SAE 8=Unavailable/ Unknown	1=Not rel. to study drug 2=Concomitant med 3=Underlying condition 4=Study drug dosing 5=Unknown 6=Other	1=Expected 2=Unexpected
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Draft

All 6 pages of Form 13A must be faxed to DCC and Principal Investigator must sign and date Form 13A, page 6.

TOLSURF FORM 13A: ADVERSE EVENTS

Dosing Period (Enrollment to 7 days after final dose)

Screening ID #	Secondary ID	Staff Initials	Randomization #
EZAH [] [] [] []	EZAACROS [] [] [] []	[] []	EZARANDN [] [] [] []
	EZASTFID [] [] [] []		

Time Point: ● Dosing Period **EZAVISIT**
39

Draft

Adverse Events	Date of Event (mm/dd/yy)	Severity	Relationship to Study Drug	Actions Taken	Outcome	Causality	Event Type
13A.31. <input checked="" type="radio"/> Other EZAOTH2 Describe "Other" event below:	[] [] / [] [] / [] [] EZAOTH2D	[]	EZAOTH2R []	[]	EZAOTH2O []	[]	EZAOTH2T []
EZAOTH2CM			EZAOTH2S	EZAOTH2A		EZAOTH2C	
		1=Mild 2=Moderate 3=Severe 4=Life-threatening 8=Unavailable/Unknown	1=Not related 2=Unlikely 3=Possible 4=Probably 5=Definitely related 8=Unavailable/Unknown	1=Not applicable 2=Study drug Discontinued 3=Standard care 8=Unavailable/Unknown	1=Recovered/Resolved 2=Improved 3=Unchanged 4=Worsened 5=Death=SAE 8=Unavailable/Unknown	1=Not rel. to study drug 2=Concomitant med 3=Underlying condition 4=Study drug dosing 5=Unknown 6=Other	1=Expected 2=Unexpected

I have reviewed all 6 pages of Form 13A and it is accurate to the best of my knowledge.

Principal Investigator Signature

Form signed? Yes No

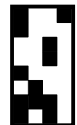
EZAPIS

EZAPII

PI Initials: [] []

[] [] / **EZAPID** [] []

Date of signature:(mm/dd/yy)



Draft

1

EZAPISD

TOLSURF FORM 13B: ADVERSE EVENTS

Discharge Period (8 days after final dose to Discharge)

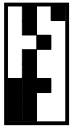
Screening ID #	Secondary ID	Staff Initials	Randomization #
EZ6ID	EZ6ACROS	EZ6STFID	EZ6RANDN

Draft

13B.1. Did any co-morbidities reported on Form 11B or adverse events occur during the Discharge Period? <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown EZ6AES	Time Point: <input checked="" type="radio"/> Discharge period EZ6VISIT
--	--

If "Yes", document below. Complete pages 1 - 4. PI must sign and date Form 13B, page 4. (See MOP)

Adverse Events	Date of Event (mm/dd/yy)	Severity	Relationship to Study Drug	Actions Taken	Outcome	Causality	Event Type
13B.2. <input checked="" type="radio"/> Death EZ6DEA	EZ6DEAD / /	EZ6DEAS	EZ6DEAR	EZ6DEAA	EZ6DEAO	EZ6DEAC	EZ6DEAT
13B.3. <input checked="" type="radio"/> Severe Cardiopulmonary Decompensation, requiring CPR with chest compressions & cardiac meds. EZ6CPR	EZ6CPRD / /	EZ6CPRS	EZ6CPRR	EZ6CPRA	EZ6CPRO	EZ6CPRC	EZ6CPRT
13B.4. <input checked="" type="radio"/> Severe PIE EZ6PIE	EZ6PIED / /	EZ6PIES	EZ6PIER	EZ6PIEA	EZ6PIEO	EZ6PIEC	EZ6PIET
13B.5. <input checked="" type="radio"/> Severe Pulmonary Hemorrhage EZ6PUL	EZ6PULD / /	EZ6PULS	EZ6PULR	EZ6PULA	EZ6PULO	EZ6PULC	EZ6PULT
13B.6. <input checked="" type="radio"/> Pneumothorax requiring chest tube EZ6PNE	EZ6PNE / /	EZ6PNES	EZ6PNER	EZ6PNEA	EZ6PNEO	EZ6PNEC	EZ6PNET
		1=Mild 2=Moderate 3=Severe 4=Life-threatening 8=Unavailable/Unknown (see MOP)	1=Not related 2=Unlikely 3=Possible 4=Probably related 5=Definitely related 8=Unavailable/Unknown	1=Not applicable 3=Standard Care 8=Unavailable/Unknown	1=Recovered/Resolved 2=Improved 3=Unchanged 4=Worsened 5=Death 8=Unavailable/Unknown	1=Not rel. to study drug 2=Concomitant med 3=Underlying condition 4=Study drug dosing 5=Unknown 6=Other	1=Expected 2=Unexpected



Draft

All 4 pages of Form 13B must be faxed to DCC and Principal Investigator must sign and date Form 13B, page 4.

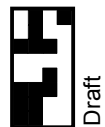
Discharge Period (8 days after final dose to Discharge)

Screening ID #	Secondary ID	Staff Initials	Randomization #
EZ7ID	EZ7ACROS	EZ7STFID	EZ7RANDN

Draft

EZ7VISIT 2 ● Time Point:
Discharge period

Adverse Events	Date of Event (mm/dd/yy)	Severity	Relationship to Study Drug	Actions Taken	Outcome	Causality	Event Type
13B.7. 1 ○ IVH EZ7IVH	EZ7IVHD	EZ7IVHS	EZ7IVHA EZ7IVHR	EZ7IVHA	EZ7IVHO	EZ7IVHC	EZ7IVHT
13B.8. 1 ○ Cystic PVL EZ7PVL	EZ7PVLD	EZ7PVLS	EZ7PVLA EZ7PVL R	EZ7PVLA	EZ7PVLO	EZ7P VLC	EZ7P VLT
13B.9. 1 ○ Hydrocephalus EZ7HYD requiring shunt	EZ7HYDD	EZ7HYDS	EZ7HYDA EZ7HYDR	EZ7HYDA	EZ7HYDO	EZ7HYDC	EZ7HYDT
13B.10. 1 ○ NEC EZ7NEC	EZ7NECD	EZ7NECS	EZ7NECA EZ7NECR	EZ7NECA	EZ7NECO	EZ7NECC	EZ7NECT
13B.11. 1 ○ Isolated EZ7GIP GI Perforation	EZ7GIPD	EZ7GIPS	EZ7GIPA EZ7GIPR	EZ7GIPA	EZ7GIPO	EZ7GIPC	EZ7GIPT
13B.12. 1 ○ Tracheomalacia EZ7MAL	EZ7MALD	EZ7MALS	EZ7MALA EZ7MALR	EZ7MALA	EZ7MALO	EZ7MALC	EZ7MALT
13B.13. 1 ○ Tracheal EZ7STE Stenosis	EZ7STED	EZ7STES	EZ7STEA EZ7STER	EZ7STEA	EZ7STEO	EZ7STEC	EZ7STET
13B.14. 1 ○ PDA Requiring EZ7PDA Treatment	EZ7PDAD	EZ7PDAS	EZ7PDAA EZ7PDAR	EZ7PDAA	EZ7PDAO	EZ7PDAC	EZ7PDAT
13B.15. 1 ○ Hypotension EZ7HYP (when treated as reported on Q11B.5.b.)	EZ7HYPD	EZ7HYPS	EZ7HYPA EZ7HYPR	EZ7HYPA	EZ7HYPO	EZ7HYPC	EZ7HYPT
		1=Mild 2=Moderate 3=Severe 4=Life-threat ening 8=Unavailable /Unknown (see MOP)	1=Not related 2=Unlikely 3=Possible 4=Probably 5=Definitely related 8=Unavailable/ Unknown	1=Not applicable 3=Standard care 8=Unavailable /Unknown	1=Recovered/ Resolved 2=Improved 3=Unchanged 4=Worsened 5=Death 8=Unavailable/ Unknown	1=Not rel. to study drug 2=Concomitant med 3=Underlying condition 4=Study drug dosing 5=Unknown 6=Other	1=Expected 2=Unexpected



Draft

All 4 pages of Form 13B must be faxed to DCC and Principal Investigator must sign and date Form 13B, page 4.

TOLSURF FORM 13B: ADVERSE EVENTS

Discharge Period (8 days after final dose to Discharge)

Screening ID #	Secondary ID	Staff Initials	Randomization #
EZ8ID	EZ8ACROS	EZ8STFID	EZ8RANDN

Draft



EZ8VISIT TIME POINT:
 Discharge period

Adverse Events	Date of Event (mm/dd/yy)	Severity	Relationship to Study Drug	Actions Taken	Outcome	Causality	Event Type
13B.16. <input type="radio"/> Pulmonary Hypertension EZ8PHY	EZ8PHYD / /	EZ8PHYS	EZ8PHYR	EZ8PHYA	EZ8PHYO	EZ8PHYC	EZ8PHYT
13B.17. <input type="radio"/> Unexpected Adverse Event EZ8UNXAE	EZ8UNXAED / / Describe AE: EZ8UNXAECM	EZ8UNXAES	EZ8UNXAER	EZ8UNXAEA	EZ8UNXAE0	EZ8UNXAEC	EZ8UNXAET
13B.18. <input type="radio"/> ROP EZ8ROP	EZ8ROPD / /	EZ8ROPS	EZ8ROPR	EZ8ROPA	EZ8ROPO	EZ8ROPC	EZ8ROPT
13B.19. <input type="radio"/> Sepsis EZ8SP1	EZ8SP1D / /	EZ8SP1S	EZ8SP1R	EZ8SP1A	EZ8SP10	EZ8SP1C	EZ8SP1T
13B.20. <input type="radio"/> Sepsis EZ8SP2	EZ8SP2D / /	EZ8SP2S	EZ8SP2R	EZ8SP2A	EZ8SP20	EZ8SP2C	EZ8SP2T
13B.21. <input type="radio"/> Sepsis EZ8SP3	EZ8SP3D / /	EZ8SP3S	EZ8SP3R	EZ8SP3A	EZ8SP30	EZ8SP3C	EZ8SP3T
13B.22. <input type="radio"/> Sepsis EZ8SP4	EZ8SP4D / /	EZ8SP4S	EZ8SP4R	EZ8SP4A	EZ8SP40	EZ8SP4C	EZ8SP4T
		1=Mild 2=Moderate 3=Severe 4=Life-threatening 8=Unavailable/Unknown (see MOP)	1=Not related 2=Unlikely 3=Possible 4=Probably 5=Definitely related 8=Unavailable/Unknown	1=Not applicable 3=Standard care 8=Unavailable/Unknown	1=Recovered/Resolved 2=Improved 3=Unchanged 4=Worsened 5=Death 8=Unavailable/Unknown	1=Not rel. to study drug 2=Concomitant med 3=Underlying condition 4=Study drug dosing 5=Unknown 6=Other	1=Expected 2=Unexpected



Draft

All 4 pages of Form 13B must be faxed to DCC and Principal Investigator must sign and date Form 13B, page 4.

TOLSURF FORM 13B: ADVERSE EVENTS

Discharge Period (8 days after final dose to Discharge)

Screening ID #	Secondary ID	Staff Initials	Randomization #
EZ9ID	EZ9ACROS	EZ9STFI	EZ9RANDN

2 ● Discharge period

Adverse Events	Date of Event (mm/dd/yy)	Severity	Relationship to Study Drug	Actions Taken	Outcome	Causality	Event Type
13B.23. <input checked="" type="radio"/> EZ9SP1 Sepsis	EZ9SP1D / /	EZ9SP1S	EZ9SP1R	EZ9SP1A	EZ9SP1O	EZ9SP1C	EZ9SP1T
13B.24. <input checked="" type="radio"/> EZ9RSV RSV Pneumonia	EZ9RSVD / /	EZ9RSVS	EZ9RSVR	EZ9RSVA	EZ9RSVO	EZ9RSVC	EZ9RSVT
13B.25. <input checked="" type="radio"/> EZ9VCP Vocal chord paralysis	EZ9VCPD / /	EZ9VCP S	EZ9VCP R	EZ9VCP A	EZ9VCP O	EZ9VCP C	EZ9VCP T
13B.26. <input checked="" type="radio"/> EZ9OTH1 Other Describe Other event below:	EZ9OTH1D / /	EZ9OTH1S	EZ9OTH1R	EZ9OTH1A	EZ9OTH1O	EZ9OTH1C	EZ9OTH1T
EZ9OTH1CM							
13B.27. <input checked="" type="radio"/> EZ9OTH2 Other Describe Other event below:	EZ9OTH2D / /	EZ9OTH2S	EZ9OTH2R	EZ9OTH2A	EZ9OTH2O	EZ9OTH2C	EZ9OTH2T
EZ9OTH2CM							

I have reviewed all 4 pages of Form 13B and it is accurate to the best of my knowledge.

EZ9PII

PI Initials: / /

Principal Investigator Signature

Form signed?

Yes No

1 EZ9PISD

Date of signature: (mm/dd/yy)
EZ9PIS / **EZ9PID** / /

1=Mild
2=Moderate
3=Severe
4=Life-threatening
8=Unavailable/Unknown (see MOP)

1=Not related
2=Unlikely
3=Possible
4=Probably related
5=Definitely related
8=Unavailable/Unknown

1=Not applicable
3=Standard care
8=Unavailable/Unknown

1=Recovered/Resolved
2=Improved
3=Unchanged
4=Worsened
5=Death
8=Unavailable/Unknown

1=Not rel. to study drug
2=Concomitant med
3=Underlying condition
4=Study drug dosing
5=Unknown
6=Other

1=Expected
2=Unexpected

Draft



Draft

TOLSURF

FORM 14A: HOSPITAL COURSE WHILE AT STUDY HOSPITAL

Screening ID #	Secondary ID	Staff Initials	Randomization #
HC1ID	HC1ACROS	HC1STFID	HC1RANDN

14A.1. TPN (Total Parenteral Nutrition):

14A.1.a. Was infant given TPN solution?

HC1TPNGVN
 Yes No

	Month	Day	Year		Month	Day	Year
14A.1.a.i. Start Date:	HC1TPNST1	/		End Date:	HC1TPNEN1	/	
14A.1.a.ii. Start Date:	HC1TPNST2	/		End Date:	HC1TPNEN2	/	
14A.1.a.iii. Start Date:	HC1TPNST3	/		End Date:	HC1TPNEN3	/	
14A.1.a.iv. Start Date:	HC1TPNST4	/		End Date:	HC1TPNEN4	/	
14A.1.a.v. Start Date:	HC1TPNST5	/		End Date:	HC1TPNEN5	/	
14A.1.a.vi. Start Date:	HC1TPNST6	/		End Date:	HC1TPNEN6	/	
14A.1.a.vii. Start Date:	HC1TPNST7	/		End Date:	HC1TPNEN7	/	
14A.1.a.viii. Start Date:	HC1TPNST8	/		End Date:	HC1TPNEN8	/	
14A.1.a.ix. Start Date:	HC1TPNST9	/		End Date:	HC1TPNEN9	/	
14A.1.a.x. Start Date:	HC1TPNST10	/		End Date:	HC1TPNEN10	/	
14A.1.a.xi. Start Date:	HC1TPNST11	/		End Date:	HC1TPNEN11	/	
14A.1.a.xii. Start Date:	HC1TPNST12	/		End Date:	HC1TPNEN12	/	
14A.1.a.xiii. Start Date:	HC1TPNST13	/		End Date:	HC1TPNEN13	/	
14A.1.a.xiv. Start Date:	HC1TPNST14	/		End Date:	HC1TPNEN14	/	

Draft





FORM 14A: HOSPITAL COURSE WHILE AT STUDY HOSPITAL

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
HC2ID	HC2ACROS	HC2STFID	HC2RANDN

14A.2. SURGERIES: (For Surgery Codes see MOP)

14A.2.a. Were any surgeries performed? Yes No

HC2SURGPER

14A.2.a.i.	Surgery Code: S	HC2SCODE1	Date:	Month	Day	Year
14A.2.a.ii.	Surgery Code: S	HC2SCODE2	Date:	Month	Day	Year
14A.2.a.iii.	Surgery Code: S	HC2SCODE3	Date:	Month	Day	Year
14A.2.a.iv.	Surgery Code: S	HC2SCODE4	Date:	Month	Day	Year
14A.2.a.v.	Surgery Code: S	HC2SCODE5	Date:	Month	Day	Year
14A.2.a.vi.	Surgery Code: S	HC2SCODE6	Date:	Month	Day	Year
14A.2.a.vii.	Surgery Code: S	HC2SCODE7	Date:	Month	Day	Year
14A.2.a.viii.	Surgery Code: S	HC2SCODE8	Date:	Month	Day	Year

14A.2.b. Have additional surgeries been performed? Yes No

HC2ADDSUR

If Yes, report these additional surgeries on FORM 14C: HOSPITAL COURSE - Additional Surgeries While at Study Hospital.

14A.3. TRANSFUSIONS: (all blood products provided by Blood Bank)

14A.3.a. Was infant given any transfusions? Yes No

HC2TRANPER

14A.3.a.i.	Date:	Month	Day	Year	Number of transfusions:	HC2TRANN1
14A.3.a.ii.	Date:	Month	Day	Year	Number of transfusions:	HC2TRANN2
14A.3.a.iii.	Date:	Month	Day	Year	Number of transfusions:	HC2TRANN3

Report additional transfusions on Form 14B - Additional Transfusions

14A.3.b. Have addition transfusions been performed? Yes No

HC2ADTRPER

Complete Form 14B: Additional Transfusions Form

14A.3.b.i. How many Form 14B: Additional Tranfusions forms were used?

HC2ADFORMN

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FORM 14B: ADDITIONAL TRANSFUSIONS

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #	Add. Trans.#
HCXID	HCXACROS	HCXSTFID	HCXRANDN	HCXADDTRAN

Each Form 14B faxed to the DCC, requires a unique number in the Add. Trans. # box above. For e.g. enter 01 on first form used, 02 on second form, 03 on third form, etc. An Add. Trans. # can only be used once. i.e. each form requires a unique #.

14B.1. ADDITIONAL TRANSFUSIONS:

14B.1.a. Were additional transfusion/s performed? Yes No
HCXTRANPER

	Month	Day	Year	
14B.1.a.i. Date:	HCXTRAND1	/		Number of transfusions: HCXTRANN1
14B.1.a.ii. Date:	HCXTRAND2	/		Number of transfusions: HCXTRANN2
14B.1.a.iii. Date:	HCXTRAND3	/		Number of transfusions: HCXTRANN3
14B.1.a.iv. Date:	HCXTRAND4	/		Number of transfusions: HCXTRANN4
14B.1.a.v. Date:	HCXTRAND5	/		Number of transfusions: HCXTRANN5
14B.1.a.vi. Date:	HCXTRAND6	/		Number of transfusions: HCXTRANN6
14B.1.a.vii. Date:	HCXTRAND7	/		Number of transfusions: HCXTRANN7
14B.1.a.viii. Date:	HCXTRAND8	/		Number of transfusions: HCXTRANN8
14B.1.a.ix. Date:	HCXTRAND9	/		Number of transfusions: HCXTRANN9
14B.1.a.x. Date:	HCXTRAND10	/		Number of transfusions: HCXTRANN10
14B.1.a.xi. Date:	HCXTRAND11	/		Number of transfusions: HCXTRANN11
14B.1.a.xii. Date:	HCXTRAND12	/		Number of transfusions: HCXTRANN12
14B.1.a.xiii. Date:	HCXTRAND13	/		Number of transfusions: HCXTRANN13
14B.1.a.xiv. Date:	HCXTRAND14	/		Number of transfusions: HCXTRANN14
14B.1.a.xv. Date:	HCXTRAND15	/		Number of transfusions: HCXTRANN15

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TOLSURF

FORM 14C: ADDITIONAL SURGERIES WHILE AT STUDY HOSPITAL

Screening ID #	Secondary ID	Staff Initials	Randomization #
HCZID	HCZACROS	HCZSTFID	HCZRANDN

14.C.1. SURGERIES: (For Surgery Codes see MOP)

HCZSURGPER

14C.1.a. Were any additional surgeries performed? Yes No

		Month	Day	Year
14C.1.a.i.	Surgery Code: S	HCZSCODE1	Date: HCZ\$DATE1	
14C.1.a.ii.	Surgery Code: S	HCZSCODE2	Date: HCZ\$DATE2	
14C.1.a.iii.	Surgery Code: S	HCZSCODE3	Date: HCZ\$DATE3	
14C.1.a.iv.	Surgery Code: S	HCZSCODE4	Date: HCZ\$DATE4	
14C.1.a.v.	Surgery Code: S	HCZSCODE5	Date: HCZ\$DATE5	
14C.1.a.vi.	Surgery Code: S	HCZSCODE6	Date: HCZ\$DATE6	
14C.1.a.vii.	Surgery Code: S	HCZSCODE7	Date: HCZ\$DATE7	
14C.1.a.viii.	Surgery Code: S	HCZSCODE8	Date: HCZ\$DATE8	
14C.1.a.ix.	Surgery Code: S	HCZSCODE9	Date: HCZ\$DATE9	
14C.1.a.x.	Surgery Code: S	HCZSCODE10	Date: HCZ\$DATE10	
14C.1.a.xi.	Surgery Code: S	HCZSCODE11	Date: HCZ\$DATE11	
14C.1.a.xii.	Surgery Code: S	HCZSCODE12	Date: HCZ\$DATE12	
14C.1.a.xiii.	Surgery Code: S	HCZSCODE13	Date: HCZ\$DATE13	
14C.1.a.xiv.	Surgery Code: S	HCZSCODE14	Date: HCZ\$DATE14	
14C.1.a.xv.	Surgery Code: S	HCZSCODE15	Date: HCZ\$DATE15	
14C.1.a.xvi.	Surgery Code: S	HCZSCODE16	Date: HCZ\$DATE16	

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FORM 15: MEDICATIONS WHILE AT STUDY HOSPITAL

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
: MD1ID	MD1ACROS	MD1STFID	: MD1RANDN

15.1 SYSTEMIC CORTICOSTEROID ADMINISTERED? Yes No Unknown
(list all courses) **MD1SYCOAD**

15.1.a. Start Date: MD1SCSTAR1 / / **Stop Date:** MD1SCSTOP1 / / **Ongoing:** **MD1STDAOG1**

Type: (select one) Dexamethasone Hydrocortisone Other **MD1SCTYPE1**

Reason(s) given: (select all that apply) BPD Adrenal insufficiency Other **MD1SCRBP1 MD1SCRAI1**

Hypotension Extubation **MD1SCRBP1 MD1SC1REX1 MD1SCROT1**

15.1.b. Start Date: MD1SCSTAR2 / / **Stop Date:** MD1SCSTOP2 / / **Ongoing:** **MD1STDAOG2**

Type: (select one) Dexamethasone Hydrocortisone Other **MD1SCTYPE2**

Reason(s) given: (select all that apply) BPD Adrenal insufficiency Other **MD1SCRBP2 MD1SCRAI2**

Hypotension Extubation **MD1SCRBP2 MD1SC1REX2 MD1SCROT2**

15.1.c. Start Date: MD1SCSTAR3 / / **Stop Date:** MD1SCSTOP3 / / **Ongoing:** **MD1STDAOG3**

Type: (select one) Dexamethasone Hydrocortisone Other **MD1SCTYPE3**

Reason(s) given: (select all that apply) BPD Adrenal insufficiency Other **MD1SCRBP3 MD1SCRAI3**

Hypotension Extubation **MD1SCRBP3 MD1SC1REX3 MD1SCROT3**

15.1.d. Start Date: MD1SCSTAR4 / / **Stop Date:** MD1SCSTOP4 / / **Ongoing:** **MD1STDAOG4**

Type: (select one) Dexamethasone Hydrocortisone Other **MD1SCTYPE4**

Reason(s) given: (select all that apply) BPD Adrenal insufficiency Other **MD1SCRBP4 MD1SCRAI4**

Hypotension Extubation **MD1SCRBP4 MD1SC1REX4 MD1SCROT4**

15.1.e. Start Date: MD1SCSTAR5 / / **Stop Date:** MD1SCSTOP5 / / **Ongoing:** **MD1STDAOG5**

Type: (select one) Dexamethasone Hydrocortisone Other **MD1SCTYPE5**

Reason(s) given: (select all that apply) BPD Adrenal insufficiency Other **MD1SCRBP5 MD1SCRAI5**

Hypotension Extubation **MD1SCRBP5 MD1SC1REX5 MD1SCROT5**

15.1.f. Start Date: MD1SCSTAR6 / / **Stop Date:** MD1SCSTOP6 / / **Ongoing:** **MD1STDAOG6**

Type: (select one) Dexamethasone Hydrocortisone Other **MD1SCTYPE6**

Reason(s) given: (select all that apply) BPD Adrenal insufficiency Other **MD1SCRBP6 MD1SCRAI6**

Hypotension Extubation **MD1SCRBP6 MD1SC1REX6 MD1SCROT6**





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FORM 15: MEDICATIONS WHILE AT STUDY HOSPITAL

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
:MD2ID	MD2STFID		
	MD2ACROS		MD2RANDN

15.2 CAFFEINE ADMINISTERED? Yes No Unknown **MD2CAFADM**
(list all courses)

	Month	Day	Year	Month	Day	Year	Ongoing:
15.2.a. Start Date:	MD2CASTRD1			MD2CASTPD1			<input checked="" type="radio"/> MD2CASTOG1
15.2.b. Start Date:	MD2CASTRD2			MD2CASTPD2			<input type="radio"/> MD2CASTOG2
15.2.c. Start Date:	MD2CASTRD3			MD2CASTPD3			<input type="radio"/> MD2CASTOG3
15.2.d. Start Date:	MD2CASTRD4			MD2CASTPD4			<input type="radio"/> MD2CASTOG4
15.2.e. Start Date:	MD2CASTRD5			MD2CASTPD5			<input type="radio"/> MD2CASTOG5
15.2.f. Start Date:	MD2CASTRD6			MD2CASTPD6			<input type="radio"/> MD2CASTOG6

15.3. CONTINUOUS INFUSION PRESSOR(S) ADMINISTERED? Yes No Unknown **MD2PRSADM**
(see MOP for definition, list all courses)

	Month	Day	Year	Month	Day	Year	Ongoing:
15.3.a. Start Date:	MD2PRSTRD1			MD2PRSTPD1			<input checked="" type="radio"/> MD2PROG1
15.3.b. Start Date:	MD2PRSTRD2			MD2PRSTPD2			<input type="radio"/> MD2PROG2
15.3.c. Start Date:	MD2PRSTRD3			MD2PRSTPD3			<input type="radio"/> MD2PROG3
15.3.d. Start Date:	MD2PRSTRD4			MD2PRSTPD4			<input type="radio"/> MD2PROG4
15.3.e. Start Date:	MD2PRSTRD5			MD2PRSTPD5			<input type="radio"/> MD2PROG5
15.3.f. Start Date:	MD2PRSTRD6			MD2PRSTPD6			<input type="radio"/> MD2PROG6
15.3.g. Start Date:	MD2PRSTRD7			MD2PRSTPD7			<input type="radio"/> MD2PROG7

15.4 VITAMIN A (administered to prevent BPD)
 Yes No Unknown **MD2VITA**

15.4.a. Start Date:			MD2VASTAR1	Stop Date:	MD2VASTOP1		<input checked="" type="radio"/> MD2VAOG1
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FORM 16A: DISCHARGE REPORT

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
DE1ID	DE1ACROS	DE1STFID	DE1RANDN

16A.1. DISCHARGED HOME FROM STUDY HOSPITAL:

16A.1.a. Was infant discharged home from study hospital? Yes No DE1HOME

16A.1.a.i. Date of discharge home: / / DE1HOMED
Month Day Year

16A.1.a.ii. Weight at discharge home: grams DE1HOMEW

16A.1.a.iii. Head circumference (to the nearest 0.5cm) at discharge home: cm DE1HOMEH

16A.1.a.iv. Respiratory status when discharged home: (select highest level of support)

<input type="radio"/> In room air	<input checked="" type="radio"/> DE1HOMEV	<input type="radio"/> Oxygen continuously
<input type="radio"/> Mechanical ventilation w/trach	<input type="radio"/> DE1HOMEV	<input type="radio"/> Oxygen intermittently

16A.1.a.v. Oxygen saturation: % DE1HOMEEO

16A.1.a.vi. Last PCO₂, within 2 weeks of discharge home: mm Hg (see MOP) Unavailable DE1HOMEP DE1HOMEP

16A.1.a.vii. BPD Medications when discharged home: (select all that apply)

<input type="radio"/> Diuretics	<input type="radio"/> Systemic steroids	<input type="radio"/> None
<input type="radio"/> Bronchodilators	<input type="radio"/> Inhaled steroids	<input type="radio"/> Unavailable
<input type="radio"/> Other	<input type="text"/>	

Multivitamin type: DE1HOMEMVS

16A.2. DISCHARGED TO OTHER HOSPITAL(OH):

16A.2.a. Was infant discharged to other hospital? Yes No DE1HOSP

16A.2.a.i. Date of discharge to other hospital: / / DE1HOSPD
Month Day Year

16A.2.a.ii. Weight at discharge to other hospital: grams DE1HOSPWT

16A.2.a.iii. Head circumference (to the nearest 0.5cm) at discharge to OH: cm DE1HOSPH

16A.2.a.iv. Respiratory status when discharged to other hospital:(select one)

<input type="radio"/> Off ventilator, off CPAP, off oxygen, off nasal cannula
<input type="radio"/> On mechanical ventilation
<input checked="" type="radio"/> DE1HOSPV
<input type="radio"/> On SiPAP, BiPAP or nasal prong ventilation
<input type="radio"/> On nasal CPAP
<input type="radio"/> On continuous nasal cannula

16A.2.a.v. FiO₂: LPM: / Effective oxygen: FiO₂: DE1HOSPFIO DE1HOSPLPM DE1HOSPEO

16A.2.a.vi. Oxygen Saturation: % DE1HOSPO

16A.2.a.vii. Last PCO₂ prior to 36 week date: mm Hg (see MOP) Unavailable DE1HOSPP DE1HOSPU





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FORM 16A: DISCHARGE REPORT

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
DE2ID	DE2ACROS	DE2STFID	DE2RANDN

16A.3. DISCHARGED HOME FROM OTHER HOSPITAL(OH):

DE2HOME

16A.3.a. Was infant discharged home from other hospital? Yes No Unknown

16A.3.a.i. Date of discharge home from OH: / / DE2HOMEDU
Month Day Year Unavailable

16A.3.a.ii. Weight at discharge home from OH: grams DE2HOMEDU
DE2HOMEDU Unavailable

16A.3.a.iii. Head circumference (to the nearest 0.5cm) at discharge home from OH: cm DE2HOMEDU
DE2HOMEDU Unavailable

16A.3.a.iv. Respiratory status when discharged home from OH: (select one) DE2HOMEDU

In Room Air → 16A.3.a.v. Date weaned to room air: / / DE2WEANDU
Month Day Year Unavailable

Oxygen Continuously

Oxygen Intermittently

Mechanical Ventilation w/trach

Unavailable

16A.3.a.vi. Oxygen saturation when discharged home from OH: % DE2HOMEDU
DE2HOMEDU Unavailable

16A.3.a.vii. Last PCO2 within 2 weeks of discharge home from OH: (see MOP) mm Hg DE2HOMEDU
DE2HOMEDU Unavailable

16A.3.a.viii. BPD Medications when discharged home from OH: (select all that apply)

Diuretics DE2HOMEDU

Systemic steroids DE2HOMEDU

None DE2HOMEDU

Bronchodilators DE2HOMEDU

Inhaled steroids DE2HOMEDU

Unavailable DE2HOMEDU

Other DE2HOMEDU

Multivitamin type: DE2HOMEDU

16A.4. AUDIOLOGY: Screening Test Prior to Discharge: DE2AUD

16A.4.a. Was audiology test performed? Yes No Unknown

16A.4.a.i. RIGHT EAR: (select one) Passed Failed Refer Not done DE2EARR

16A.4.a.ii. LEFT EAR: (select one) Passed Failed Refer Not done DE2EARL

16A.5. OPTHAMOLOGIC: DE2ROP

16A.5.a. Was ROP screening performed? Yes No Unknown (see MOP)

16A.5.a.i. ROP Classification: (worst stage observed in either eye) DE2ROPCLAS

No ROP Stage 1 Stage 2 Stage 3

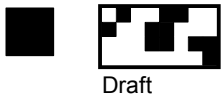
Stage 4 Stage 5 Unknown Not Applicable

If ROP Stage 1 - 5, enter on Form 13B: Adverse Events, Q13B.19.

16A.5.a.ii. Was ROP surgery performed? Yes No Unknown DE2ROPSUR

16A.5.a.iii. Date of surgery: / / DE2ROPSUR
Month Day Year Enter on Form 14, Hospital Course, Q14A.2.

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FORM 16B: HOSPITAL DISCHARGE BREATHING OUTCOME QUESTIONNAIRE

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
DP1ID	DP1ACROS	DP1STFID	DP1RANDN

This information to be collected from parent/guardian at time of discharge from study hospital and faxed to the DCC with other discharge forms.

Was interview conducted? **DP1INTCON**

1 Yes → Date questionnaire completed: **DP1COMP** / /
Month Day Year

0 No → **DP1NOINTR**
0 Child died **1** Unable to contact family **2** Family refused

16B.1. Information received from (list primary caregiver): (select one) DP1INFOFM

1 Mother **2** Father **3** Grandparent **4** Foster Parent **5** Other

16B.2. How many people normally live in your home including your baby (for at least 6 months of the year)? (select one) DP1INH

1 2 - 3 **2** 4 - 6 **3** 7 - 10 **4** > 10

16B.2.a. Are there any children < 5 years of age (other than your baby) that live in the home?

DP1CINH **0** None **1** 1 - 2 **2** 3 - 5 **3** 6 - 8 **4** > 8

16B.3. Do you have any pets? (select all that apply)

DP1PNONE None **DP1PCAT** Dog **DP1PCAT** Cat **DP1PCAT** Other furry animals **DP1PFISH** Fish **DP1POTH** Birds **DP1POTH** Other _____
DP1PDOG **DP1PFRY** **DP1PBIRD**

16B.4. Infant feeds: (select one)

DP1FEEDS
1 Breast milk only **3** Breast milk and formula **5** Other
2 Formula only **4** No enteral feedings

16B.5. Will your child receive any care outside the home in the next year? DP1OCARE

1 Yes **0** No **8** Unknown

<p>16B.5.a. Who will provide care? (select all that apply)</p> <p>DP1CRLTV DP1CDC DP1CFRND DP1COTH 1 <input type="radio"/> Relatives 1 <input type="radio"/> Daycare 1 <input type="radio"/> Friends 1 <input type="radio"/> Other</p>
<p>16B.5.b. Will other children that are not siblings be present at outside care site?</p> <p>1 <input type="radio"/> Yes 0 <input type="radio"/> No 8 <input type="radio"/> Unknown DP1OCLD</p>

16B.6. Please describe the situation regarding smoking in your child's home: (select one)

16B.6.a. Which one of the following statements best describes the situation regarding smoking in your child's home? **DP1SMKSIT**

- 1** Smoking is allowed in any room in the home
- 2** Smoking is limited to part of the house where the child will rarely go
- 3** Occasionally there is smoking inside the house (visitor, family member)
- 4** There is no smoking inside the house at all
- 5** Other

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FORM 16B: HOSPITAL DISCHARGE BREATHING OUTCOME QUESTIONNAIRE

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
DP2ID	DP2ACROS	DP2STFID	DP2RANDN

16B.6.b. Does either parent smoke? Yes No Unknown **DP2PSMK**

16B.6.b.i. Estimated number of cigarettes per day: **DP2PSMKPD**
 < 5 5 - 10 11 - 20 > 1 pack/day Unknown

16B.6.c. All together, how many people who live in the home smoke? **DP2PHSMK**
 None 1 - 2 > 2 Unknown

16B.6.d. Will your child travel regularly (at least once a week) in a vehicle (car or truck) that someone smokes in, even when the child is not in the car? **DP2INCAR**
 Yes No Unknown

16B.7. Please tell us what breathing and allergy problems run in the family.

- 16B.7.a. Biological parents - one or both: *(select all that apply)*
- | | | |
|--|--|---|
| <input checked="" type="radio"/> Asthma/recurrent lung infections DP2BPAS | <input type="radio"/> Medication allergies DP2BPMAL | <input type="radio"/> Other DP2BPOTH |
| <input type="radio"/> Allergies (allergies/hayfever) DP2BPAL | <input type="radio"/> Eczema DP2BPEC | <input type="radio"/> None DP2BPNON |
- 16B.7.b. Grandparents - one or both: *(select all that apply)*
- | | | |
|---|--|---|
| <input type="radio"/> Asthma/recurrent lung infections DP2GPAS | <input type="radio"/> Medication allergies DP2GPMAL | <input type="radio"/> Other DP2GPOTH |
| <input type="radio"/> Allergies (allergies/hayfever) DP2GPAL | <input type="radio"/> Eczema DP2GPEC | <input type="radio"/> None DP2GPNON |
- 16B.7.c. Siblings - one or both: *(select all that apply)*
- | | | |
|---|--|---|
| <input type="radio"/> Asthma/recurrent lung infections DP2SBAS | <input type="radio"/> Medication allergies DP2SBMAL | <input type="radio"/> Other DP2SBOTH |
| <input type="radio"/> Allergies (allergies/hayfever) DP2SBAL | <input type="radio"/> Eczema DP2SBEC | <input type="radio"/> None DP2SBNON |

16B.8. Please tell us more about your baby's background:

- 16B.8.a. Maternal education: *(select one)* **DP2MATEDU**
- | | | |
|---|--|---|
| <input type="radio"/> Some education, High School not completed | <input type="radio"/> Some College | <input type="radio"/> Graduate study |
| <input checked="" type="radio"/> High School graduate | <input type="radio"/> College graduate | <input type="radio"/> Unknown/Unavailable |
- 16B.8.b. Paternal education: *(select one)* **DP2PATEDU**
- | | | |
|---|--|---|
| <input type="radio"/> Some education, High School not completed | <input type="radio"/> Some College | <input type="radio"/> Graduate study |
| <input checked="" type="radio"/> High School graduate | <input type="radio"/> College graduate | <input type="radio"/> Unknown/Unavailable |
- 16B.8.c. How will your child's health care be paid for? *(select one)* **DP2PAY**
- | | | |
|---|--|---|
| <input type="radio"/> Private Insurance | <input checked="" type="radio"/> Medicaid/Public | <input type="radio"/> No Insurance (self pay) |
|---|--|---|



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FORM 17: DEATH REPORT

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
: DH1ID	DH1ACROS	DH1STFID	DH1RANDN

17.1. Did infant die? **DH1DIED**

- Yes **1**
 No **0**
 Unknown **8**

Form complete. PI must still sign and date page 2.

17.1.a. Date of Death: **DH1DOD**

/ /
 Month Day Year

17.1.b. How many days after dosing with study drug/sham did death occur? **DH1DOSING**

1 ≤ 7 days

Enter death on Form 13A: Adverse Events, Q13A.2. and Form 21: Serious Adverse Events, Q21.1.

2 > 7 days

Enter death on Form 13B: Adverse Events, Q13B.2. only. Do **NOT** enter this death on Form 21: Serious Adverse Events

8 Unknown

17.2. Where did infant die? **DH1WHERE**

- Study hospital **1**
 Home **2**
 Other hospital **3**

17.3. Primary Cause of Death: (select one) **DH1CDP**

- Sepsis **0** Pulmonary Hypertension **3** IVH **2**
 Respiratory Disease **1** Pulmonary Hemorrhage **4** NEC **6**
 Other - specify below: **7** Cardiopulmonary Arrest **5** Unknown **8**

DH1CDPOCM

17.4. Secondary Cause(s) of Death: (select all that apply)

- Sepsis **1** **DH1CDSSEP** Pulmonary Hypertension **1** **DH1CDSPHY** IVH **1** **DH1CDSIVH**
 Respiratory Disease **1** **DH1CDSRES** Pulmonary Hemorrhage **1** **DH1CDSPHE** NEC **1** **DH1CDSNEC**
 Other - specify below: **1** **DH1CDSOTH** Cardiopulmonary Arrest **1** **DH1CDSCA** Unknown **1** **DH1CDSUNK**

DH1CDSOCM

17.5. Was life support withdrawn? **DH1LIFESUP**

- Yes **1**
 No **0**
 Unknown **8**





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FORM 17: DEATH REPORT

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

DH2RSD

17.6. What is the relationship of death to study drug/sham: (select one)

- 1 Not related
 2 Unlikely
 8 Unavailable/Unknown
 4 Probably related
 5 Definitely related
 3 Possibly related

17.6.a. Type of death: (review MOP instructions)

- 1 Expected
 2 Unexpected

DH2TYPE

17.7. Was an autopsy performed?

- 1 Yes
 0 No
 8 Unknown

DH2AUTOP

17.7.a. Date of autopsy:

/ /
Month Day Year

DH2AUTOPD

17.7.b. Enter Cause of Death and Pulmonary autopsy findings below:

DH2AUFIND

Principal Investigator Signature

Principal Investigator Initials:

DH2PII

Form signed? 1 Yes 0 No

DH2PIS

Date of signature:

/ /
Month Day Year

DH2PID

1 DCC ONLY: Confirm PI signature and date

DH2PISD



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FORM 18: PROTOCOL DEVIATIONS

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #	PD Tracking #
PD1ID	PD1ACROS	PD1STFID	PD1RANDN	PD1TRACKN

Fax Form 18: Protocol Deviations to the DCC as deviations occur. At least one Form 18, pgs 1 & 2, is required for each infant. The PI must sign and date page 2 of each Form 18 submitted. Each time there is a Protocol Deviation, complete pages 1 & 2. Enter the same PD Tracking # on both pages. For e.g. 1st PD Tracking # will be 01, 2nd PD Tracking # will be 02, etc. The same PD Tracking # cannot be used on more than one set of forms.

PD1PRODEV

18.1 **HAS THERE BEEN A PROTOCOL DEVIATION(S)?** Yes No Unknown

18.2 **WHAT IS THE PROTOCOL DEVIATION(S):** (select all that apply)

PD1OXC

18.2.a. Failure to perform oxygen reduction challenge.

Describe:

PD1OXCDES

18.2.b. iNO administration deviated from NO CLD protocol DURING iNO treatment.

PD1INODU

(see Form 6, Q6.1.b.)

Document details of **HIGHEST** iNO dose administered DURING iNO treatment:

Highest concentration(during)	Highest iNO start date (during)	Highest iNO end date (during)
PD1INODUC PPM	PD1INODUSD Month Day Year	PD1INODUED Month Day Year

18.2.c. Additional iNO administered AFTER completing iNO course per NO CLD Protocol.

PD1INOAF

(see Form 6, Q6.2b.)

Document details of **HIGHEST** additional iNO dose administered AFTER iNO treatment per NO CLD protocol.

Highest concentration(after)	Highest iNO start date (after)	Highest iNO end date (after)
PD1INOAFUC PPM	PD1INOAFSD Month Day Year	PD1INOAFED Month Day Year

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FORM 18: PROTOCOL DEVIATIONS

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #	PD Tracking #
<input type="text"/> PD2ID	<input type="text"/> PD2ACROS	<input type="text"/> PD2STFID	<input type="text"/> PD2RANDN	<input type="text"/> PD2TRACKN

SEE TOP OF PAGE 1 FOR DCC INSTRUCTIONS REGARDING THIS FORM.
 A PD TRACKING # IS REQUIRED ABOVE. FORM WILL BE NOT BE ACCEPTED BY THE DCC, IF THIS BOX IS BLANK.

1 18.2.d. Deviation from Clinical Guidelines: (see MOP)
PD2CLGDL

Specify:

PD2CLGPDCM

Date of this Protocol Deviation: / /
Month Day Year **PD2CLGDLD**

1 18.2.e. Other Protocol Deviation: **PD2OTHPD**

Specify:

PD2OTHPDCM

Date of this Protocol Deviation: / /
Month Day Year **PD2OTHPDD**

 Principal Investigator Signature Principal Investigator Initials: **PD2PII**

Form signed: **1** Yes **0** No /
PD2PID Date of signature: (mm/dd/yy)

1 DCC ONLY: Confirm PI signature and date **PD2PISD**



FORM 19: PROTOCOL VIOLATIONS

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #	Tracking #
PV1ID	PV1ACROS PV1STFID		PV1RANDN	PV1TRACKN

From Post Enrollment - Discharge: Fax Form 19: Protocol Violations to the DCC as violations occur. At least one Form 19, pgs 1 & 2, is required for each infant.

Enter the same number in the Tracking # box on pages 1 & 2 of this form. Note: tracking #s cannot be used on more than one form. i.e. one Tracking # per Form 19 (pgs 1 & 2)

For e.g. enter 01 for the first faxed form, 02 for the second, 03 for the third, etc.

19.1 **HAS THERE BEEN A PROTOCOL VIOLATION(S)?** Yes No Unknown
PV1PROV

19.2 **WHAT IS THE NATURE OF THE PROTOCOL VIOLATION(S):** (select all that apply)

19.2.a. Randomized but all Inclusion Criteria were NOT met. **PV1INCNMET**

Select Inclusion Criteria NOT met:

PV1IGA Gestational age ≤ 28 weeks gestation

PV1IAGE Between 7 and 14 days of age.

PV1INT7T14 Infant intubated and mechanically ventilated between 7 - 14 days of life?

PV1PLTRINO Plan to treat with Inhaled Nitric Oxide?

19.2.a.i. Date of this Protocol Violation: / /
Month Day Year **PV1ICNMD**

19.2.b. Randomized but Exclusion Criteria were present. **PV1EXCPRES**

Select Exclusion Criteria present:

PV1SCMCA Serious congenital malformations or chromosomal abnormalities

PV1LEL Life expectancy < 7 seven days, starting at DOL 7

PV1CLINUNS Clinically unstable

PV1IVH Bilateral Grade 4 intracranial hemorrhage

PV1TSUR Less than 48 hrs from last dose of early surfactant

PV1EPTDATA Unlikely to be able to collect primary endpoint data at 36 weeks.

19.2.b.i. Date of this Protocol Violation: / /
Month Day Year **PV1EXCPRED**

19.2.c. Consent not obtained in accordance with IRB guidelines.

PV1COIRBN

19.2.c.i. Date of this Protocol Violation: / /
Month Day Year **PV1COIRBND**





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FORM 19: PROTOCOL VIOLATIONS

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #	PV Tracking #
PV2ID	PV2ACROS	PV2STFID	PV2RANDN	PV2TRACKN

SEE TOP OF PAGE 1 FOR DCC INSTRUCTIONS REGARDING THIS FORM. A PV TRACKING # IS REQUIRED ABOVE. FORM WILL BE NOT BE ACCEPTED BY THE DCC, IF THIS BOX IS BLANK.

(Continuation of Q19.2)

1 19.2.d. Unblinding of study personnel.
PV2UNBLPR
 Date of this Protocol Violation: / /
Month Day Year

1 19.2.e. Study drug administration or dosing error.
PV2SDEROR Dose: #1 #2 #3 #4 #5
PV2SDERDS
 Date of this Protocol Violation: / /
Month Day Year

1 19.2.f. Withdrawal from study protocol for any reason.
PV2WDPRO
 Date of this Protocol Violation: / /
Month Day Year
 Describe:

1 19.2.g. iNO not administered.
PV2INONGV
 Date of this Protocol Violation: / /
Month Day Year
 Describe:

1 19.2.h. Open label surfactant administered.
PV2OLSGVN
 Date of this Protocol Violation: / /
Month Day Year

Principal Investigator Signature _____ Principal Investigator Initials:
 Form signed: Yes No **PV2PIS** /
Date of signature:(mm/dd/yy)
1 PV2PISD

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FORM 20: EARLY TERMINATION / PERMANENT DISCONTINUATION OF MEDICATION

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
ETDID	ETDACROS	ETDSTFID	ETDRANDN

AN INFANT CAN EITHER PERMANENTLY DISCONTINUE STUDY DRUG/SHAM BUT REMAIN IN THE STUDY or TERMINATE EARLY BY DISCONTINUING ALL STUDY INVOLVEMENT

20.1. Has infant discontinued study participation? Yes No Unknown
ETDDISC

20.1.a. Current discontinuation status: (select one)

ETDTYPE

Discontinued study drug/sham but remains in study

Discontinued ALL study activities

20.1.a.i. Reason discontinued study drug/sham:

ETDDMR

- Parent request
- Adverse Event
- Serious Adverse Event
- Protocol violation or lack of compliance
- Physician request
- Other - Specify below:

ETDDMOCM

20.1.a.ii. Date discontinued study drug/sham:

Month / Day / Year
ETDDMD

20.1.b.i. Reason discontinued study:

ETDDAR

- Consent withdrawn
- Physician request
- Other - Specify below:

ETDDAOCM

20.1.b.ii. Date discontinued study:

Month / Day / Year
ETDDAD

Principal Investigator Signature

Principal Investigator Initials: ETDPPI

Form signed: Yes No ETDPIS

Date of signature

Month / Day / Year
ETDPID

DCC ONLY: Confirm PI signature and date
ETDPISD

FORM 21: SERIOUS ADVERSE EVENTS TOLSURF

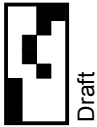
Screening ID #	Secondary ID	Staff Initials	Randomization #	SAE #
SE1ID	SE1ACROS	SE1STFID	SE1RANDN	SE1SAEN

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INSTRUCTIONS: Report all Serious Adverse Events that occurred since administration of study drug/sham. Enter a unique SAE# above (beginning with "001") and enter this SAE# in infant SAE log. Each infant can have multiple SAE Forms. If no SAEs, number this Form "SAE 001", and fill in "No" bubble that No SAE occurred.

Has a Serious Adverse Event listed below occurred since administration of study drug/sham? Yes No **SE1SAE**
 If "Yes", document below. Complete pages 1 - 4. PI must sign all 4 pages of this form.

SERIOUS ADVERSE EVENTS	REPORTED TO IRB	DATE OF EVENT (mm/dd/yy)	SEVERITY	RELATIONSHIP TO STUDY DRUG	ACTION TAKEN	OUTCOME	CAUSALITY	TYPE
21.1 SE1DEA <input checked="" type="radio"/> Death - That occurred ≤ 7 days after study drug dose/sham	<input type="radio"/> Yes 1 <input type="radio"/> No 0 SE1DEAI	[][] / [][] / [][] SE1DEAD Enter Description on page 3, Q21.1.a.	<input type="radio"/> SE1DEAS	<input type="radio"/> SE1DEAR	<input type="radio"/> SE1DEAA	<input type="radio"/> SE1DEAO	<input type="radio"/> SE1DEAC	<input type="radio"/> SE1DEAT
21.2 SE1RES <input checked="" type="radio"/> Severe Respiratory Decompensation (defined as RSS > 5 above baseline for > 24 hrs) - That occurred ≤ 4 hours after study drug dose/sham	<input type="radio"/> Yes 1 <input type="radio"/> No 0 SE1RESI	[][] / [][] / [][] SE1RESD Enter Description on page 3, Q21.2.a.	<input type="radio"/> SE1RESS	<input type="radio"/> SE1RESR	<input type="radio"/> SE1RESA	<input type="radio"/> SE1RESO	<input type="radio"/> SE1RESC	<input type="radio"/> SE1REST
21.3 SE1CPR <input checked="" type="radio"/> Severe Cardiopulmonary Decompensation requiring CPR with chest compressions and cardiac medication - That occurred ≤ 4 hours after study drug dose/sham	<input type="radio"/> Yes 1 <input type="radio"/> No 0 SE1CPRI	[][] / [][] / [][] SE1CPRD Enter Description on page 3, Q21.3.a.	<input type="radio"/> SE1CPRS	<input type="radio"/> SE1CPRR	<input type="radio"/> SE1CPRA	<input type="radio"/> SE1CPRO	<input type="radio"/> SE1CPRC	<input type="radio"/> SE1CPRT
			1=Mild 2=Moderate 3=Severe 4=Life-threatening 8=Unavailable/Unknown	1=Not related 2=Unlikely 3=Possible 4=Probably related 5=Definitely related 8=Unavailable/Unknown	1=Not applicable 2=Study Drug discontinued. 3=Standard Care 8=Unavailable/Unknown	1=Recovered/Resolved 2=Improved 3=Unchanged 4=Worsened 5=Death=SAE 8=Unavailable/Unknown	1=Not related to study drug 2=Concomitant med 3=Underlying condition 4=Study drug dosing 5=Unknown 6=Other	1=Expected 2=Unexpected



Draft

All 4 pages of Form 21 must be faxed to DCC and Principal Investigator must sign and date Form 21, page 4.

FORM 21: SERIOUS ADVERSE EVENTS TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #	SAE #
SE2ID	SE2ACROS	SE2STFID	SE2RANDN:	SE2SAEN

Draft



SERIOUS ADVERSE EVENTS	REPORTED TO IRB	DATE OF EVENT (mm/dd/yy)	SEVERITY	RELATIONSHIP TO STUDY DRUG	ACTION TAKEN	OUTCOME	CAUSALITY	TYPE of EVENT
21.4 SE2PIE 1 <input type="radio"/> Severe PIE That occurred ≤ 24 hours after study drug dose/sham	SE2PIEI 1 <input type="radio"/> Yes 0 <input type="radio"/> No	SE2PIED / / <i>Enter Description on page 4, Q21.5.a.</i>	SE2PIES <input type="checkbox"/>	SE2PIER <input type="checkbox"/>	<input type="checkbox"/>	SE2PIEO <input type="checkbox"/>	<input type="checkbox"/>	SE2PIET <input type="checkbox"/>
21.5 SE2PUL 1 <input type="radio"/> Severe Pulmonary Hemorrhage That occurred ≤ 24 hours after study drug dose/sham	SE2PULI 1 <input type="radio"/> Yes 0 <input type="radio"/> No	SE2PULD / / <i>Enter Description on page 3, Q21.4.a.</i>	SE2PULS <input type="checkbox"/>	SE2PULR <input type="checkbox"/>	<input type="checkbox"/>	SE2PULO <input type="checkbox"/>	<input type="checkbox"/>	SE2PULT <input type="checkbox"/>
21.6 SE2PNE 1 <input type="radio"/> Pneumothorax requiring Chest Tube That occurred ≤ 24 hours after study drug dose/sham	SE2PNEI 1 <input type="radio"/> Yes 0 <input type="radio"/> No	SE2PNED / / <i>Enter Description on page 4, Q21.6.a.</i>	SE2PNES <input type="checkbox"/>	SE2PNER <input type="checkbox"/>	<input type="checkbox"/>	SE2PNEO <input type="checkbox"/>	<input type="checkbox"/>	SE2PNET <input type="checkbox"/>
21.7 SE2UNXAE 1 <input type="radio"/> Unexpected Adverse Event That is related to and occurred within 7 days of study drug dose/sham.	SE2UNXAEI 1 <input type="radio"/> Yes 0 <input type="radio"/> No	SE2UNXAED / / <i>Enter Description on page 4, Q21.7.a.</i>	SE2UNXAES <input type="checkbox"/>	SE2UNXAER <input type="checkbox"/>	<input type="checkbox"/>	SE2UNXAE O <input type="checkbox"/>	<input type="checkbox"/>	SE2UNXAET <input type="checkbox"/>
			1=Mild 2=Moderate 3=Severe 4=Life-threatening 8=Unavailable/Unknown	1=Not related 2=Unlikely 3=Possible 4=Probably 5=Definitely related 8=Unavailable/Unknown	1=Not applicable 3=Standard Care 8=Unavailable/Unknown	1=Recovered/Resolved 2=Improved 3=Unchanged 4=Worsened 5=Death=SAE 8=Unavailable/Unknown	1=Not related to study drug) 2=Concomitant med 3=Underlying condition 4=Study drug dosing 5=Unknown 6=Other	1=Expected 2=Unexpected



Draft

All 4 pages of Form 21 must be faxed to DCC and Principal Investigator must sign and date Form 21, page 4.

FORM 21: SERIOUS ADVERSE EVENTS TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #	SAE #
SE3ID	SE3ACROS	SE3STFID	SE3RANDN	SE3SAEN

Draft

Narrative record of Serious Adverse Event

Please briefly describe SAE. Also copy physician's progress notes from the incident and fax with cover sheet to UCSF/CC, attn. Roberta Ballard at 415-514-8150.

21.1.a - Death - Description:

SE3DEACM

21.2.a - Severe Respiratory Decompensation - Description:

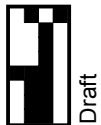
SE3RESCM

21.3.a - Severe Cardiopulmonary Decompensation requiring CPR with chest compressions and cardiac meds: Description:

SE3CPRCM

21.4.a - Severe Pulmonary Hemorrhage - Description:

SE3PULCM



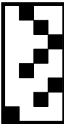
Draft

All 4 pages of Form 21 must be faxed to DCC and Principal Investigator must sign and date Form 21, page 4.

FORM 21: SERIOUS ADVERSE EVENTS TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #	SAE #
SE4ID	SE4ACROS	SE4STFID	SE4RANDN	SE4SAEN

Draft



Narrative record of Serious Adverse Event

Please briefly describe SAE. Also copy physician's progress notes from the incident and fax with cover sheet to UCSF/CC, attn. Roberta Ballard at 415-514-8150.

21.5.a - Severe PIE - Description:

SE4PIECMT

21.6.a - Pneumothorax with chest tube - Description:

SE4PNECMT

21.7.a - Unexpected Adverse Event related to and occurred within 7 days of study drug dose/sham - Description:

SE4UXAECMT

I have reviewed all 4 pages of Form 21 and it is accurate to the best of my knowledge.

Principal Investigator Signature

Principal Investigator Initials:

SE4PII

Form signed? Yes No

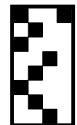
SE4PIS

Date of signature (mm/dd/yy)

SE4PID

DCC ONLY: Confirm PI signature and date

SE4PISD



Draft



FORM 23: BREATHING OUTCOMES INTERVAL QUESTIONNAIRE

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
DP3ID	DP3STFID	DP3ACROS	DP3RANDN

23.1. Corrected age at current interview: **DP3VISIT**
 3 Months 6 Months 9 Months 12 Months 18 Months

History of last interview

23.2. Date of last interview: **DP3LASTD**
 / /
Month Day Year

23.3. Which interview was the last one conducted? **DP3LASTAGE**
 1 Discharge 3 3 Months 6 6 Months 9 9 Months 12 12 Months 18 18 Months

23.4. Was an interview conducted for the current period (Q23.1)? **DP3INTDONE**

1 Yes

23.4.a. Date of this interview: **DP3INTDOND**

/ /
Month Day Year

Conduct interview

0 No

23.4.b. Reason this interview was not conducted: (select one)

- DP3NOINTRS**
- 1 Child died
 - 2 Unable to contact
 - 3 Family refused this contact
 - 5 Consent withdrawn. No further follow-up
 - 4 Other

Describe:

Form is complete. (see MOP)

23.5. Information on this form received from: (select one) **DP3FROM**

- 1 Mother 2 Father 3 Grandparent 4 Foster Parent 5 Other

Draft



FORM 23: BREATHING OUTCOMES INTERVAL QUESTIONNAIRE

TOLSURF

DP4VISIT

Screening ID #	Secondary ID	Staff Initials	Randomization #
DP4ID	DP4STFID		DP4RAND
DP4ACROS			

Corrected age 3 Months 6 Months 9 Months 12 Months 18 Months

23.6. Since discharge (or last interview), has your child had a cough without a cold?

Yes No **DP4COUGH**

23.6.a. How often do you notice a cough without a cold? (select one) **DP4COUGHOF**

- Every day
- Not every day but more than once per week
- Once a week
- Not every week

23.6.b. When does your child have this cough without a cold: (select one) **DP4COUGHWH**

- More often during the day
- The same amount whether it is day or night
- More often at night

23.7. Since discharge (or last interview), has a medical person (nurse or doctor) told you he/she heard wheezing when listening to your child's chest? **DP4WHEEZ**

Yes No

23.7.a. When has a medical person heard wheezing in your child's chest? (select one)

- Only when my child has had a cold **DP4WHEEZWH**
- Only when my child has not had a cold
- Both when my child has had a cold and without a cold

23.8. Since discharge (or last interview), has your child been treated in the Emergency Department or by another doctor in the office or clinic because of a breathing problem or a change in his/her breathing? **DP4ER**

Yes No

23.8.a. How many times was your child treated in the Emergency Department, office or clinic? **DP4ERN**

- ≤ 2
- 3 - 5
- 6 - 10
- > 10

23.9. Since discharge (or last interview), has your child been admitted to the hospital overnight? **DP4HOSP**

Yes No

23.9.a. How many times was your child admitted to the hospital overnight? **DP4HOSPOVN**

23.9.b. How many times was this because of a breathing problem or a change in his/her breathing? **DP4HOSPB RN**





FORM 23: BREATHING OUTCOMES INTERVAL QUESTIONNAIRE

TOLSURF

DP5VISIT

Screening ID #	Secondary ID	Staff Initials	Randomization #
DP5ID	DP5ACROS	DP5STFID	DP5RANDN

Corrected age: 3 Months 6 Months 9 Months 12 Months 18 Months

23.10. Is your child currently on oxygen or a breathing machine (ventilator) at home?

Yes
DP5RESP

23.10.a. Is child currently on oxygen? Yes No DP5RESPYO

23.10.b. Is child currently on a ventilator? Yes No DP5RESPYV

No

23.10.c. Has your child been on oxygen at home since discharge (or last interview)? Yes No DP5RESPNO

23.10.d. Has your child been on a ventilator at home since discharge (or last interview)? Yes No DP5RESPNV

23.11. Since discharge (or last interview), has your child been diagnosed with a respiratory syncytial virus (RSV) infection? DP5RSV

Yes No

23.12. Which of these medications has your child been prescribed (at home or in the hospital) since discharge (or last interview)? (select all that apply)

A) Inhaled bronchodilators DP5INBRON

D) Systemic steroids DP5SYSTEMER

B) Inhaled steroids DP5INSTER

E) Pulmonary vasodilators DP5PULVAS

C) Diuretics DP5DIUR

F) None of the above DP5NOTA

See Medication list on last page

23.12.1. Has your child taken any vitamins or supplements that contain Vitamin D (since discharge or last interview)? DP5VITD

Yes No

See Medication list on last page

Draft





FORM 23: BREATHING OUTCOMES INTERVAL QUESTIONNAIRE

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
DP6ID	DP6ACROS	DP6STFID	DP6RANDN

Corrected age **3** 3 Months **6** 6 Months **9** 9 Months **12** 12 Months **18** 18 Months

23.13. How many people normally live in your home including your baby (for at least 6 months of the year)? (select one) **DP6HOMENUM**

1 2 - 3 **2** 4 - 6 **3** 7 - 10 **4** > 10

DP6HOMECHL 23.13.a. Are there any children < 5 years of age (other than your baby) that live in the home?

0 None **1** 1 - 2 **2** 3 - 5 **3** 6 - 8 **4** > 8

23.14. Do you currently have any pets? (select all that apply)

DP6PNONE None **DP6PCAT** Dog **DP6PCAT** Cat **DP6PFISH** Other furry animals **DP6PFISH** Fish **DP6POTH** Birds **DP6POTH** Other
DP6PDOG Dog **DP6PFRY** Fish **DP6PBIRD** Birds

Complete Qs 23.15.a. & 23.15.b. below, only if this is a 6 or a 12 Months Interview

23.15.a. What type of milk does your child drink? (select one) **DP6MILKTYP**

1 Breast milk only **3** Breast milk and formula **5** Other
2 Formula only **4** No enteral feedings

23.15.b. Was breast milk discontinued since last interview? **DP6BMKDS**

1 Yes **0** No

23.15.b.i. How old (in months) was the child when breast milk was discontinued? (approximate corrected age in months) **DP6BMKMO**

		months
--	--	--------

Complete Q23.16 below, only if this is an 18 Month Interview

23.16. Is child currently still taking some breast milk? **DP6BMK18**

1 Yes **0** No

23.16.a. Was breast milk discontinued since last interview? **DP6BMKDS18**

1 Yes **0** No

23.16.a.i. How old (in months) was the child when breast milk was discontinued? (approximate corrected age in months) **DP6BMKMO18**

		months
--	--	--------

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FORM 23: BREATHING OUTCOMES INTERVAL QUESTIONNAIRE

TOLSURF
DP7VISIT

Screening ID #	Secondary ID	Staff Initials	Randomization #
DP7ID	DP7ACROS	DP7STFID	DP7RANDN

Corrected age: 3 Months 6 Months 9 Months 12 Months 18 Months

23.17. Does your child receive any care outside the home? **DP7CARE**

Yes No

23.17.a. Who provides care? (select all that apply)			
<input checked="" type="radio"/> Relatives DP7CAREWRE	<input checked="" type="radio"/> Daycare DP7CAREWFR	<input type="radio"/> Friends DP7CAREWOT	<input type="radio"/> Other
23.17.b. Are other children that are not siblings present at outside care site?			
<input checked="" type="radio"/> Yes <input type="radio"/> No		DP7CAREWDC	
DP7CAREOTH			

23.18. Please describe the situation regarding smoking in your child's home.

23.18.a. Which one of the following statements best describes the situation regarding smoking in your child's home? (select one) **DP7SMKHOM**

- Smoking is allowed in any room in the home
- Smoking is limited to part of the house where the child will rarely go
- Occasionally there is smoking inside the house (visitor, family member)
- There is no smoking inside the house at all
- Other

23.18.b. Does either parent smoke? Yes No Don't know

DP7SMKPAR

23.18.b.i. Estimate number of cigarettes per day: DP7SMKNCIG				
<input checked="" type="radio"/> < 5	<input type="radio"/> 5 - 10	<input type="radio"/> 11 - 20	<input type="radio"/> > 1 pack/day	<input type="radio"/> Unknown

23.18.c. Altogether, how many people who live in the home smoke? **DP7SMKNUM**

None 1 - 2 > 2

23.18.d. Does your child travel regularly (at least once a week) in a vehicle (car or truck) that someone smokes in, even when the child is not in the car? **DP7SMKCAR**

Yes No

Draft



FORM 23: BREATHING OUTCOMES INTERVAL QUESTIONNAIRE

TOLSURF
DP8VISIT

Screening ID #	Secondary ID	Staff Initials	Randomization #
DP8ID	DP8ACROS	DP8STFID	DP8RANDN

Corrected age: ● 18 Months **18**

23.19. Has your child ever had hay fever or another condition that makes his/her nose or eyes runny, stuffy or itchy without a cold? **DP8HAYFVR**

1 Yes **0** No

23.20. Has your child ever been allergic to any food? (these are reactions that include rash and swelling, not vomiting or diarrhea) **DP8ALLRGFD**

1 Yes **0** No

23.21. Has your child ever been allergic to any medicine (these are reactions that include rash and swelling, not vomiting or diarrhea) **DP8ALLRGMD**

1 Yes **0** No

23.22. Has your child ever had eczema diagnosed by a doctor (allergic skin rash)? **DP8ECZEMA**

1 Yes **0** No

23.23. Has your child been diagnosed with asthma by a doctor? **DP8ASTHMA**

1 Yes **0** No

Draft

TOLSURF

FORM 23: BREATHING OUTCOMES
INTERVAL QUESTIONNAIRE

MEDICATIONS REFERENCE SHEET

INTERVIEWER NOTE:

BELOW ARE EXAMPLES OF THE MEDICATIONS LISTED ON Q23.12:

A) INHALED BRONCHODILATORS

- 1) Albuterol (Ventolin)
- 2) levoalbuterol (Xopenex)
- 3) ipratropium bromide (Atrovent)

B) INHALED STEROIDS

- 1) beclomethasone (Beclivent, Qvar, and Vanceril)
- 2) budesonide (Pulmicort)
- 3) flunisolide (Aerobid)
- 4) fluticasone (Flovent)
- 5) triamcinolone (Azmacort)

C) DIURETICS

- 1) furosemide (Lasix)
- 2) chlorothiazide or hydrochlorothiazide
(Diuril or Hydrodiuril)
- 3) aldactone

D) SYSTEMIC STEROIDS

- 1) cortisone
- 2) dexamethasone
- 3) prednisone
- 4) prednisolone
- 5) methylprednisolone

E) PULMONARY VASODILATORS

- 1) sildenafil (Revatio)
- 2) tadalafil (Adcirca)
- 3) bosentan (Tracleer)
- 4) ambrisentan (Myogen)
- 5) inhaled iloprost (Ventavis)
- 6) beraprost
- 7) trepopostinil
- 8) epoprostenol (Flolan)
- 9) inhaled nitric oxide

INTERVIEWER NOTE:

BELOW ARE EXAMPLES OF THE MEDICATIONS REFERRED TO ON Q23.13:

VITAMINS OR VITAMIN SUPPLEMENTS

- 1) Polyvisol with/without iron
- 2) Trivisol with/without iron
- 3) D-visol
- 4) Multivitamin drops
- 5) Children's Complete chewable vitamins/multivitamin, with/without iron and with/without calcium:
Centrum
Flinstones
Bugs Bunny
Pokeman
Scooby Doo
- 6) Lil' Critters



FORM 24: NEURODEVELOPMENTAL FOLLOW-UP EXAM

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
ND1ID	ND1ACROS	ND1STFID	ND1RANDN

Corrected age at current exam: **12** 12 Months **24** 24 Months **ND1VISIT**

24.1. Details of this Neurodevelopmental Exam:

24.1.a. Was this interview done? **1** Yes **0** No
ND1EXADONE

Go to Question 24.1.b.

24.1.a.i. Reason this interview was not done: (select one) **ND1NOEXARS**

- 1** Child died
- 2** Unable to contact
- 3** Family refused this contact
- 5** Consent withdrawn. No further follow-up
- 6** Family moved out of area of follow-up clinic (no telephone # available)
- 4** *Other → Describe: **ND10THDES**

Do not complete any further questions on this form.

* If "Other" is selected, contact CCC Droject Director for form completion instructions.

24.1.b. Where was child evaluated? (select one)

ND1EVAL

- 1** At follow-up clinic
- 2** Over the telephone →
- 3** In hospital as in-patient

24.1.b.i. Reason evaluated over the phone: (select one)

- 1** Moved out of area of follow-up clinic site
- 2** Could not schedule follow-up clinic visit

4 Other Specify: **ND1EVALSP**

24.1.c. Date of this interview: / / **ND1EVALD**
Month Day Year

ND1REL
 24.2. Information received from: (select one)

1 Mother **2** Father **3** Grandparent **4** Foster Parent **5** Other

Draft



FORM 24: NEURODEVELOPMENTAL FOLLOW-UP EXAM

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
ND2ID	ND2ACROS	ND2STFID	ND2RANDN

Corrected age at current exam: 12 Months 24 Months **ND2VISIT**

24.3. Family/Social history at time of assessment.

24.3.a. Living arrangement: (select one) **ND2LVAR**

- 1 One parent
- 2 Two parents
- 3 Foster home
- 4 Other → Describe:

ND2LVDES

24.3.b. Primary Language spoken in the home: (select one) **ND2LANG**

- 1 English spoken as first language
- 2 English spoken as second language. Specify 1st language:
- 3 English spoken very little or not at all. Specify 1st language:
- 8 Unknown

ND2ENG2ND

ND2ENGNOT

24.3.c. Maternal education: (select one) **ND2MATEDU**

- 1 Some education, high school not complete
- 2 High school graduate
- 3 Some college
- 4 College graduate
- 5 Graduate study
- 8 Unknown/Unavailable

24.3.d. Maternal employment: (select one) **ND2MATEMP**

- 1 Employed as: Specify:
- 2 Full time homemaker
- 3 Student
- 4 Unemployed
- 8 Unknown

ND2MATEMSP

24.4. Medical history at time of assessment.

24.4.a. Since initial hospitalization or last follow-up exam, has child received any of the following diagnoses or surgeries? (select all that apply)

- ND2GAST** Gastrostomy tube placement
- ND2VENT** Ventriculoperitoneal shunt placement
- ND2SEIZ** Seizure disorder requiring treatment
- ND2FAIL** Failure to thrive
- ND2TYMP** Tympanostomy tube placement
- ND2EYE** Eye surgery
- ND2PDA** PDA ligation or other closure of PDA
- ND2NODI** No diagnoses, or surgeries received since initial hospitalization or last follow-up exam

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FORM 24: NEURODEVELOPMENTAL FOLLOW-UP EXAM

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
ND3ID	ND3ACROS	ND3STFID	ND3RANDN

Corrected age at current exam: 12 12 Months 24 24 Months ND3VISIT

24.4.b. How many times has child been hospitalized for non-respiratory illness or surgery? (total hospitalizations, including those identified on Question 24.4.a.)

Total number of hospitalizations: ND3HOSN 1 None 1 N/A (infant still in hospital)
ND3HOSNONE

ANSWER QUESTION 24.4.c. AT 12 MONTHS and 24 MONTHS EXAM

24.4.c. Is child currently taking any of the following medications for a chronic medical condition? (select all that apply)

- 1 Anti-reflux medications ND3ANTIRE
- 1 Prokinetics ND3PROK
- 1 Anti-epileptics ND3ANTIEP
- 1 Other Specify: ND3OTHSP
- 1 Not taking any medications listed above ND3NOT

See Medication list on last page

ANSWER QUESTION 24.4.d. AT 24 MONTHS EXAM

24.4.d.i. Which of the medications below has child been prescribed (at home or in the hospital) since the 12 Months interview? (select all that apply)

- 1 A) Inhaled bronchodilators ND3INBRON
- 1 B) Inhaled steroids ND3INSTER
- 1 C) Diuretics ND3DIUR
- 1 D) Systemic steroids ND3SYSTER
- 1 E) Pulmonary vasodilators ND3PULVAS
- 1 F) Vitamins/supplements containing Vit.D ND3VITD
- 1 None of the above ND3NOTA

See Medication list (A - F) on last page

24.4.d.ii. Has your child ever had hay fever or another condition that makes his/her nose or eyes runny, stuffy or itchy without a cold?	1 <input type="radio"/> Yes 0 <input type="radio"/> No	ND3HAYFVR
24.4.d.iii. Has your child ever been allergic to any food? (these are reactions that include rash and swelling, not vomiting or diarrhea)	1 <input type="radio"/> Yes 0 <input type="radio"/> No	ND3ALLRGFD
24.4.d.iv. Has your child ever been allergic to any medicine? (these are reactions that include rash and swelling, not vomiting or diarrhea)	1 <input type="radio"/> Yes 0 <input type="radio"/> No	ND3ALLRGMD
24.4.d.v. Has your child ever had eczema diagnosed by a doctor? (allergic skin rash)	1 <input type="radio"/> Yes 0 <input type="radio"/> No	ND3ECZEMA
24.4.d.vi. Has your child been diagnosed with asthma by a doctor?	1 <input type="radio"/> Yes 0 <input type="radio"/> No	ND3ASTHMA

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FORM 24: NEURODEVELOPMENTAL FOLLOW-UP EXAM

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
ND4ID	ND4ACROS ND4STFID		ND4RANDN

Corrected age at current exam: **12** 12 Months **24** 24 Months **ND4VISIT**

24.4.e. Milestones:

24.4.e.i. Is child able to sit alone without support? **ND4SIT** **1** Yes **0** No

24.4.e.i.a. Corrected age at which child sat alone without support: **ND4AGESIT** months

24.4.e.ii. Is child able to walk independently? **ND4WALK** **1** Yes **0** No

24.4.e.ii.a. Corrected age at which child walked independently: **ND4AGEWALK** months

24.5. Child's growth parameters at time of assessment:

24.5.a. Weight (kg): **ND4WEIGHT** . 24.5.b. Recumbent Length (cm): **ND4LENGTH** .

24.5.c. Head circumference (cm): **ND4HEAD** .

24.6. Child's vision at time of assessment:

24.6.a. Visual function: (select one) **ND4VISFUNC**
1 Normal **2** Unilateral blindness **3** Bilateral blindness **4** Prescription glasses

24.6.b. Visual problems at time of assessment: (select one) **ND4VISPROB**

- 1** None **5** Cataracts
- 2** Strabismus **6** Glaucoma
- 3** Cortical blindness **7** Retinal detachment
- 4** Optic atrophy **8** Other Specify: **ND4VIOTHSP**

24.7. Child's hearing:

24.7.a. Hearing function: (select one) **ND4HEAR**

- 1** Normal
- 2** Unilateral hearing loss → 24.7.a.i. Requires amplification? **ND4UNIAMP** **1** Yes **0** No
- 3** Bilateral hearing loss → 24.7.a.ii. Requires amplification? **ND4BILAMP** **1** Yes **0** No





FORM 24: NEURODEVELOPMENTAL FOLLOW-UP EXAM

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
ND5ID	ND5ACROS	ND5STFID	ND5RANDN

Corrected age at current exam: 12 Months 24 Months

24.8. Modified Gross Motor Function Test: **ND5GMFDONE**

24.8.1. Was the Modified Gross Motor Function Test performed? Yes No

Complete questions below to establish child's Gross Motor Function level.

24.8.2. Can child walk 10 steps independently? **ND5STEPS**

No Yes

24.8.2.a. Can child sit? (may use hands for support) **ND5GMFSIT**

Yes No

24.8.2.a.i. Can child do all of the following? **ND5GMFALL**

1 - Crawl on hands/knees with reciprocal leg movements
2 - Pull to stand
3 - Cruise

Yes No

24.8.2.b. Does child have gait abnormalities? **ND5GMFGAIT**

Yes No

24.8.2.a.ii. Does child have head control in both supported sitting and rolls? **ND5GMFHEAD**

Yes No

24.9. Has a physician diagnosed this child with cerebral palsy? **ND5CP**

Yes No Unknown

24.9.1. Cerebral palsy is characterized by: (select one) **ND5CPTYPE**

1 Diplegia 2 Hemiplegia 3 Quadriplegia 4 Other

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FORM 24: NEURODEVELOPMENTAL FOLLOW-UP EXAM

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
ND6ID	ND6ACROS	ND6STFD	ND6RANDN

Corrected age at current exam: ²⁴ 24 Months **ND6VISIT**

DO NOT PERFORM THE BAYLEY INFANT DEVELOPMENT III TEST IF THIS NEURODEVELOPMENTAL EXAM IS COMPLETED OVER THE TELEPHONE.

24.10. Bayley Scale of Infant Development III:

24.10.1. Did child perform the Bayley Infant Development III test? **ND6BSIDONE** Yes No

24.10.1.a. Reason(s) test not done: *(select all that apply)*

<input checked="" type="radio"/> Visual impairment ND6VISIMP	<input type="radio"/> Parent refused ND6REFUSE
<input checked="" type="radio"/> Hearing impairment ND6HEARIMP	<input type="radio"/> Severe behavior disorder ND6BEHDIS
<input checked="" type="radio"/> Child did not cooperate with several exam attempts ND6NOCOOP	<input type="radio"/> Severe developmental delay ND6DEVDEL
<input checked="" type="radio"/> Other. Specify: ND6OTH <input type="text" value="ND6OTHSP"/>	<input type="radio"/> Exam done over the phone ND6PHONE

THIS PAGE IS COMPLETE, GO TO NEXT PAGE

24.10.2. Was this test administered in English? Yes No **ND6ENGLISH**

24.10.2.a. Was an interpreter used? Yes No **ND6INTERP**

24.10.3. Date test done: / / **ND6BSIDD**
Month Day Year

24.10.4. Bayley Scoring:

24.10.4.a. Cognitive Composite score: **ND6CCS**

24.10.4.b. Language Composite score: **ND6LCS**

24.10.4.b.i. Receptive Language scaled score: **ND6RLSS**

24.10.4.b.ii. Expressive Language scaled score: **ND6ELSS**

24.10.4.c. Motor Composite score: **ND6MCS**

24.10.4.c.i. Gross Motor scaled score: **ND6GMSS**

24.10.4.c.ii. Fine Motor scaled score: **ND6FMSS**

24.10.5. BSID III Examiner signature: _____

24.10.5.a. Is this page signed? Yes No **ND6SIG** Date signed: / / **ND6SIGD**
Month Day Year

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FORM 24: NEURODEVELOPMENTAL FOLLOW-UP EXAM

TOLSURF

Screening ID #	Secondary ID	Staff Initials	Randomization #
ND7ID	ND7ACROS	ND7STFI	ND7RANDN

Corrected age at current exam: 24 24 Months ND7VISIT

24.11. M-CHAT- If parent unable to completed at the Clinic Follow-up Visit, please complete by telephone.

24.11.1. Date if completed by parent at Clinic Follow-up visit: <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="radio"/> Not done <small>Month Day Year</small> ND7CLIND / ND7CLINNOT	24.11.1.a. Date if completed over the telephone: <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="radio"/> Not done <small>Month Day Year</small> ND7PHOMED / ND7PHONNOT
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Please fill out the following questions about how your child usually is. Please try to answer every question. If the behavior is rare (e.g., you've only seen it once or twice), please answer as if the child does not do it.

QUESTIONS	YES	NO	No answer
24.11.2. Does your child enjoy being swung, bounced on your knee, etc.? ND7SWUNG	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.3. Does your child take an interest in other children? ND7OTHCHLD	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.4. Does your child like climbing on things, such as up stairs? ND7CLIMB	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.5. Does your child enjoy playing peek-a-boo/hide-and-seek? ND7PLAY	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.6. Does your child ever pretend, for example, to talk on the phone or take care of dolls, or pretend other things? ND7PRETEND	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.7. Does your child ever use his/her index finger to point, to ask for something? ND7ASK	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.8. Does your child ever use his/her index finger to point, to indicate interest in something? ND7INTERST	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.9. Can your child play properly with small toys (e.g., cars or bricks) without just mouthing, fiddling, or dropping them? ND7TOYS	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.10. Does your child ever bring objects over to you (parent) to show you something? ND7SHOW	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.11. Does your child look you in the eye for more than a second or two? ND7EYE	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.12. Does your child ever seem oversensitive to noise? (e.g., plugging ears) ND7NOISE	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.13. Does your child smile in response to your face or your smile? ND7SMILE	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.14. Does your child imitate you? (e.g., if you make a face, will your child imitate it?) ND7IMITATE	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.15. Does your child respond to his/her name when you call? ND7NAME	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.16. If you point at a toy across the room, does your child look at it? ND7POINT	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.17. Does your child walk? ND7WALK	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.18. Does your child look at things you are looking at? ND7LOOK	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.19. Does your child make unusual finger movements near his/her face? ND7FINGER	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.20. Does your child try to attract your attention to his/her own activity? ND7ATTRACT	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.21. Have you ever wondered if your child is deaf? ND7DEAF	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.22. Does your child understand what people say? ND7SAY	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.23. Does your child sometimes stare at nothing or wander with no purpose? ND7STARE	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
24.11.24. Does your child look at your face to check your reaction when faced with something unfamiliar? ND7CHECK	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

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