PECARN
Pediatric Emergency Care Applied Research Network

Screening Log ID Number

__ __ - __ __ __ __ __

Site ID # Screening Log ID #

A Bronchiolitis Enrollment Criteria

A. Inclusion/Exclusion Criteria

Inclusion Criteria	Yes	No	
2. First time wheezing or respiratory distress			**If NO,** STOP HERE
3. Age 60 days or greater, but less than 12 months			**If NO,** STOP HERE
4. English or Spanish speaking			**If NO,** STOP HERE

If any inclusion criteria are NO, stop here. Discontinue patient screening, patient is not eligible.

Exclusion Criteria	Yes	No	
5. PMH bronchitis, bronchiolitis, wheezing, asthma, RAD, or use of albuterol > 7d prior to today			**If YES,** STOP HERE
6. Prior adverse reaction to dexamethasone			**If YES,** STOP HERE
7. Any steroid medication taken in the past 14 days			**If YES,** STOP HERE
8. Known Heart Disease			**If YES,** STOP HERE
9. Known Lung Disease			**If YES,** STOP HERE
10. Premature Birth (< 36 weeks gestational age)			**If YES,** STOP HERE
11. Immune Suppression or Deficiency			**If YES,** STOP HERE
12. Chicken Pox (active or exposed within 14 days)			**If YES,** STOP HERE

If any exclusion criteria are YES, stop here. Discontinue patient screening, patient is not eligible.

Qualifying Vital Signs Time (24 hour clock, Midnight 00:00)

__ __ : __ __ ☐ Not Available

Hour Minute

Temperature __ __ __ . __ ☐ Not Available

Heart Rate __ __ __ ☐ Not Available

Respiratory Rate __ __ ☐ Not Available

Room Air Saturation (O_2Sat) __ __ __ % ☐ Not Available

Qualifying RDAI Time (24 hour clock, Midnight 00:00)

__ __ : __ __ ☐ Not Available

Hour Minute

RDAI: __ __ ☐ Not Available

Assess Severity

13. **If mild** (RDAI < 6) check this box ☐ and **stop here**. Patient is not eligible

Enrollment in Study

14. **If parent(s)/guardian(s) decline enrollment**, check this box ☐ and **stop here**. Patient is not eligible

After obtaining parent/guardian signature on consent form, assign Patient Study ID Number and please proceed.

15. **If child needs ET tube or ICU admission *before study med* can be given,** check this box ☐ and **stop here**. Patient is not eligible

If all the above criteria are met, patient is eligible for study. Continue filling out the following forms: B. Patient Information, C. Bronchiolitis Clinical Data, and D. Chart Follow-up.

Date of Visit __ __ / __ __ / __ __ __ __

Month Day Year

Date of Birth __ __ / __ __ / __ __ __ __

Month Day Year

RA or PI Initials __ __ __

Patient Study ID Number __ __ - __ __ __ __

Site ID # Study ID #

Vial Number __ __ __ __ __ __

For Randomization Use

FOR PUBLIC RELEASE

Patient Study ID Number

☐☐ - ☐☐☐☐

Site ID # Study ID #

B
Bronchiolitis
Patient Information

1. Patient Information

First Name: _____ Last Name: _____

Date of Visit

☐☐ / ☐☐ / ☐☐☐☐

Month Day Year

Medical Record Number

☐☐☐☐☐☐☐☐☐

2. Contact Information

Parent/Guardian: _____ Relationship to Patient: _____

Parent/Guardian Phone Number

☐☐☐ - ☐☐☐ - ☐☐☐☐ Ext. _____

Cell Phone Number

☐☐☐ - ☐☐☐ - ☐☐☐☐ Ext. _____

Beeper/Pager Number

☐☐☐ - ☐☐☐ - ☐☐☐☐ Ext. _____

Other Phone Number

☐☐☐ - ☐☐☐ - ☐☐☐☐ Ext. _____

Other Contact : _____ Relationship to Patient: _____

Other Contact Phone Number

☐☐☐ - ☐☐☐ - ☐☐☐☐ Ext. _____

Other Contact Phone Number

☐☐☐ - ☐☐☐ - ☐☐☐☐ Ext. _____

Contact Notes (For RA follow-up use only)

_____

_____

_____

_____

_____

_____

Patient Study ID Number

☐☐ - ☐☐☐☐

Site ID # Study ID #

C1
Bronchiolitis
Clinical Data

A. Demographics

Date of Birth ☐ Not Documented

☐☐ / ☐☐ / ☐☐☐☐

Month Day Year

Gender

☐ Male
☐ Female

Race (obtain from chart)

☐ White
☐ Black
☐ Asian
☐ Pacific Islander
☐ American Indian/Alaskan Native
☐ Stated Unknown
☐ Other _____
☐ Not Documented

Ethnicity (obtain from chart)

☐ Hispanic
☐ Non-Hispanic
☐ Stated Unknown
☐ Not Documented

Date of Visit ☐ Not Documented

☐☐ / ☐☐ / ☐☐☐☐

Month Day Year

B. Clinical History

	Yes	No	Unknown
Family history of asthma	☐	☐	☐
History of eczema in patient	☐	☐	☐
Smokers at home	☐	☐	☐
Pets at home	☐	☐	☐

Patient Study ID Number

☐☐ - ☐☐☐☐

Site ID # Study ID #

C. Drug Administration

Vial Number

☐☐☐☐☐☐

Time Consent Signed (24 hour clock, Midnight 00:00)

☐☐ : ☐☐

Hour Minute

Place Vial Sticker Here

Time Drug Given (24 hour clock, Midnight 00:00)

☐☐ : ☐☐

Hour Minute

Weight: ☐☐.☐ kg

Dose: ☐☐ 1 ml / kg, rounded off; max 12 ml

Did the child vomit within 20 minutes of taking medication? ☐ Yes → **If YES,** complete AE form ☐ No ☐ Not Available ☐ Unknown

D. Treatment

Aerosol Treatments

	Yes	No	Number of Treatments	Continuous
Albuterol / Levalbuterol aerosol	☐	☐	☐☐	☐
Epinephrine aerosol	☐	☐	☐☐	

If both, which was used FIRST?

☐ Albuterol aerosol
☐ Epinephrine aerosol

	Yes	No	Unknown
Supplemental oxygen given any time during 4 hour observation	☐	☐	☐
Virology done	☐	☐	☐
Chest x-ray done	☐	☐	☐

E. Observation Examinations

One Hour After Time Drug First Given

1 hour Vital Signs Time (24 hour clock, Midnight 00:00)
__ : __ ☐ Not Available
Hour Minute

Temperature ___.__ ☐ Not Available
Heart Rate ___ ☐ Not Available
Respiratory Rate __ ☐ Not Available
Room Air Saturation (O_2Sat) ___ % ☐ Not Available

1 hour RDAI Time (24 hour clock, Midnight 00:00) RDAI: __
__ : __ ☐ Not Available ☐ Not Available
Hour Minute

Four Hours After Time Drug First Given

4 hour Vital Signs Time (24 hour clock, Midnight 00:00)
__ : __ ☐ Not Available
Hour Minute

Temperature ___.__ ☐ Not Available
Heart Rate ___ ☐ Not Available
Respiratory Rate __ ☐ Not Available
Room Air Saturation (O_2Sat) ___ % ☐ Not Available

4 hour RDAI Time (24 hour clock, Midnight 00:00) RDAI: __
__ : __ ☐ Not Available ☐ Not Available
Hour Minute

F. Disposition

Time of Decision to Admit or Discharge
(24 hour clock, Midnight 00:00)

__ : __ ☐ Not Available
Hour Minute

Disposition (check one)

☐ Home
☐ OR
☐ Admit: general inpatient
☐ Admit: short-stay (< 24 hour)/observation unit
☐ ICU
☐ Death in ED
☐ Transferred to _____ Name of hospital
☐ Left against medical advice

☐ Other (Describe): _____

Did patient complete ED observation as intended? ☐ Yes ☐ No ☐ Not Available

If NO, give reason (check first box that applies; check only one box):

☐ ET intubation during observation*
☐ ICU admission during observation*
☐ Early admission (before 4 hours)**
☐ Early discharge (before 4 hours)**
☐ Parent withdrew from study**
☐ Left without completing treatment**
☐ Left against medical advice**

☐ Other (specify): _____

**Complete a Serious Adverse Event Form*
***Complete protocol deviation form*

Patient Study ID Number

☐☐ - ☐☐☐☐☐

Site ID # Study ID #

D
Bronchiolitis
Follow-up

A. Chart Follow-up

Viral Result (check one)

- ☐ Not Done
- ☐ Positive (check all that apply)
  - ☐ RSV
  - ☐ Influenza
  - ☐ Parainfluenza
  - ☐ Other Virus
- ☐ Negative
- ☐ Report not available

Chest X-ray (check one)

- ☐ Not Done
- ☐ Normal (unremarkable)
- ☐ Consistent with bronchiolitis (words such as air trapping, nonspecific changes, hyperinflation, perihilar infiltrates, peribronchial thickening, patchy infiltrates, atelectasis, streaky infiltrates, or streaking.)
- ☐ Lobar or segmental infiltrate specifically mentioning possible bacterial pneumonia
- ☐ Other
- ☐ Report not available

B. Parent/Guardian Follow-up

Date Parent/Guardian Follow-up Completed

☐☐ / ☐☐ / ☐☐☐☐

Month Day Year

- ☐ Reached, but declined interview
- ☐ Patient considered unreachable / lost to follow-up (after all reasonable attempts over 3 to 4 days)

_____

Signature and date of RA completing follow-up

Initial Admission

1. Patient admitted during initial study ED visit? ☐ Yes → Go to question 2 ☐ No → Skip to question 3

2. **If Admitted Initially**, what day did your child go home?

Date Discharged ☐ Still Admitted (If checked, complete SAE form) **IF NOT INITIALLY ADMITTED,** answer question 3 below

☐☐ / ☐☐ / ☐☐☐☐

Month Day Year

3. **If Not Admitted**, was your child later admitted to a hospital? ☐ Yes ☐ No

If YES, what day? (complete SAE form)

Date Admitted ☐ Not Documented

☐☐ / ☐☐ / ☐☐☐☐

Month Day Year

Hospital Name if not same institution: _____

If YES, what was the diagnosis or problem at that time?

_____

If NO, did your child need to make an *unscheduled* visit to the doctor or emergency department since you went home from the first visit?

- ☐ Yes → Please record date below (complete AE form)
- ☐ No

Date of Visit ☐ Not Documented

☐☐ / ☐☐ / ☐☐☐☐

Month Day Year

If YES, what was the diagnosis or problem at that time?

_____

4. At anytime after leaving the ED was your child given any other steroid medicine? (decadron, orapred, pediapred, prelone etc.) ☐ Yes ☐ No ☐ Unknown

5. I'm going to read you a statement and ask you to respond: "The study medicine was helpful to my child." *Do you:* (check one)

Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree
☐	☐	☐	☐

If not answered: ☐ Not Sure ☐ Refuse/Unable to answer

Patient Study ID Number

☐☐ - ☐☐☐☐
Site ID # Study ID #

E1
Adverse Event
Reporting Form

Non-Serious Adverse Event Reporting Form

Adverse Event (AE): Any unfavorable and unintended sign or event , symptom, or disease temporally associated with the use of an investigational drug product, whether or not considered related to the investigational drug product. Complete one form for each adverse event. See AE reporting instructions for more details.

***If** event is fatal, life-threatening, disabling, requires hospitalization or prolongs hospitalization you **do not** need to fill out this form. Please complete the **Serious Adverse Event Reporting Form** instead.*

1. Description of Event _____
Provide diagnosis or sign/symptom when possible

Date of Event ☐ Not Documented
☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

Time of Event (24 hour clock, midnight is 00:00)
☐☐ : ☐☐ ☐ Unknown ☐ Not applicable
Hour Minute

For PC or PI use only.

2. Was the event related to the study drug? (check one)

☐ Unrelated *(no reasonable temporal relationship)*
☐ Possibly related

Possibly related if any **one** of these:
1. has a reasonable temporal relationship to intervention
2. could not readily have been produced by the research participant's clinical state
3. could not readily have been due to environment or other interventions
4. follows a known pattern of response to intervention

☐ Probably related

Probably related if **3** of these:
1. has a reasonable temporal relationship to intervention
2. could not readily have been produced by the clinical state, environment, or other interventions
3. follows a known pattern of response to intervention
4. disappears or decreases with reduction in dose or cessation of intervention

☐ Definitely related (*highly unlikely in this study due to single dose of study drug)*

Definitely related if ***all 4*** of these:
1. has a reasonable temporal relationship to intervention
2. could not readily have been produced by the clinical state or environmental or other interventions,
3. follows a known pattern of response to intervention,
4. disappears or decreases with reduction in dose or cessation of intervention and recurs with re-exposure.

3. Grade severity of the event.

☐ Mild (transient, no special treatment or intervention)
☐ Moderate (alleviated with simple therapeutic treatment)
☐ Severe (requires therapeutic intervention, but no hospitalization)

4. What was the outcome?

☐ Resolved; patient discharged to home
☐ Improving; patient discharged to home
☐ No change; patient discharged to home
☐ Patient admitted to hospital for bronchiolitis
☐ Unknown
☐ Ongoing

Participating Clinician or Principal Investigator Signature: _____

Patient Study ID Number

☐☐ - ☐☐☐☐
Site ID # Study ID #

E2
Adverse Event
Reporting Form

Serious Adverse Event Reporting Form

Serious Adverse Event (SAE): If event is fatal, life-threatening, is disabling or requires hospitalization or prolongs hospitalization then complete SAE form and fax to study coordinator. Complete one form for each Serious Adverse Event and fax to the Study Coordinator at (801) 585-3243 within 7 days. See AE reporting instructions for more details.

***If** event is **NOT** fatal, life-threatening, disabling, requires hospitalization or prolongs hospitalization you **do not** need to fill out this form. Please complete the **Non-Serious Adverse Event Reporting Form** instead.*

Important Note: <u>For this study</u>, initial hospitalization for Bronchiolitis will be reported in aggregate and does not require completion of this form. If the admission is for an event or diagnosis other than Bronchiolitis, you must complete this form. Please note that your local IRB may have additional reporting requirements.

1. Description of Event *(Provide diagnosis or sign/symptom when possible)*

_____

_____

_____

Date of Event ☐ Not Documented
☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

Time of Event (24 hour clock, midnight is 00:00)
☐☐ : ☐☐ ☐ Unknown ☐ Not applicable
Hour Minute

Discharge Date ☐ Not Documented
☐☐ / ☐☐ / ☐☐☐☐
Month Day Year

For PC or PI to complete. PI must review.

2. Check if SAE is one of the following:

☐ Significant GI Bleeding ☐ Excessive agitated behavior ☐ Significant hypertension

3. Was the Serious Adverse Event unexpected? ☐ Yes* ☐ No

(Unexpected: an SAE that is not consistent with the risk information described in the protocol or consent form.)

4. Was the event related to the study drug? (check one)

☐ Unrelated *(no reasonable temporal relationship)*
☐ Possibly related

Possibly related if any **one** of these:
1. has a reasonable temporal relationship to intervention
2. could not readily have been produced by the research participant's clinical state
3. could not readily have been due to environment or other interventions
4. follows a known pattern of response to intervention

☐ Probably related

Probably related if **3** of these:
1. has a reasonable temporal relationship to intervention
2. could not readily have been produced by the clinical state, environment, or other interventions
3. follows a known pattern of response to intervention
4. disappears or decreases with reduction in dose or cessation of intervention

☐ Definitely related (*highly unlikely in this study due to single dose of study drug)*

Definitely related if ***all 4*** of these:
1. has a reasonable temporal relationship to intervention
2. could not readily have been produced by the clinical state or environmental or other interventions,
3. follows a known pattern of response to intervention,
4. disappears or decreases with reduction in dose or cessation of intervention and recurs with re-exposure.

5. What was the outcome? (RA may complete)

☐ Resolved; patient discharged to home
☐ Improving; patient discharged to home
☐ No change; patient discharged to home
☐ Patient admitted to hospital for bronchiolitis
☐ Patient admitted to hospital after discharged to home or admitted for specific adverse event (eg. irregular heart rhythm)
☐ Worsening; admitted to PICU
☐ Deceased
☐ Unknown
☐ Ongoing

I certify that I have reviewed this event. _____
Principal Investigator Signature

In all cases, fax to Study Coordinator: (801) 585-3243 within 72 hrs.

***IF** unexpected SAE, fax to Study Coordinator **and** DSMB Monitor: (916) 734-5333 **within 24 hrs**.

Summary Changes to Bronchiolitis Case Report Forms
Resulting in Version 4, 9/20/05

Form A. Enrollment: 1) removed statement/signature line for participating clinician to certify that the patient has disease consistent with Bronchiolitis.

Form B. Patient Information: NO CHANGES

Form C. Clinical Data: 1) removed question from C1, section B. Clinical History: Number of days illness present, including today. 2) NO CHANGES to C2 or C3

Form D. Follow-up:1) added signature line and date for research assistant completing follow-up telephone call.

Form E. AE Reporting: 1) NO CHANGES to E1; 2) added note about local IRB reporting requirements for AE/SAE; 3) added discharge date; 4) changed DSMB monitor fax number.